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(54) **VASCULAR REMODELING DEVICE**

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See application file for complete search history.

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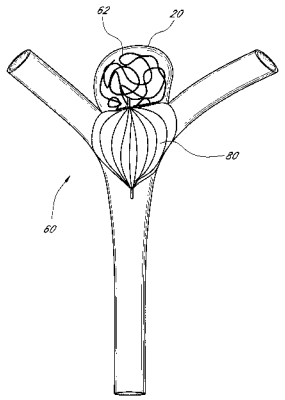
(57) **ABSTRACT**

A generally spherical vascular remodeling device is permanently positionable at a junction of afferent and efferent vessels of a bifurcation having an aneurysm. After positioning the device at the junction to substantially conform the device to the shape of the junction, the device acts as a scaffolding to inhibit herniation of objects out of the aneurysm and the device permits perfusion to the efferent vessels. Positioning the device may include deployment and mechanical or electrolytic release from a catheter. Embolic material may be inserted in the aneurysm before or after positioning the device. The device may have a first end, a second end substantially opposite to the first end, and a plurality of filaments extending between and coupled at the first end and the second end. Such devices may be football shaped, pumpkin shaped, or twisted. The device may include a plurality of loops forming a generally spherical shape.

15 Claims, 25 Drawing Sheets



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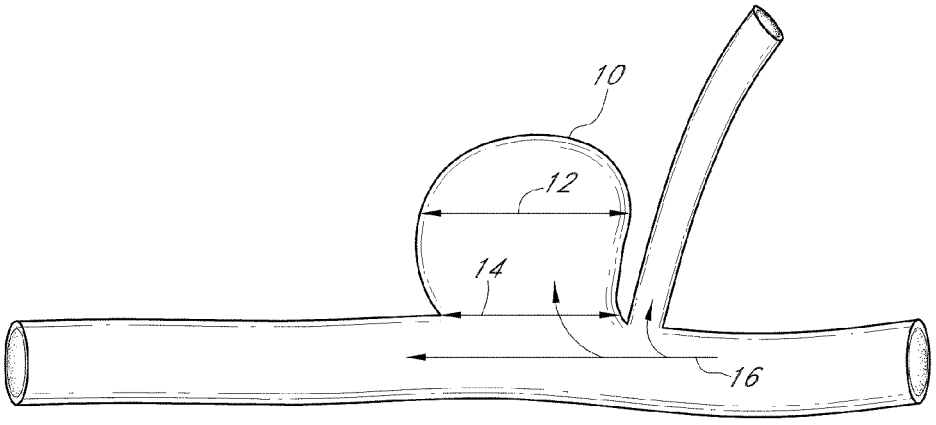

FIG. 1

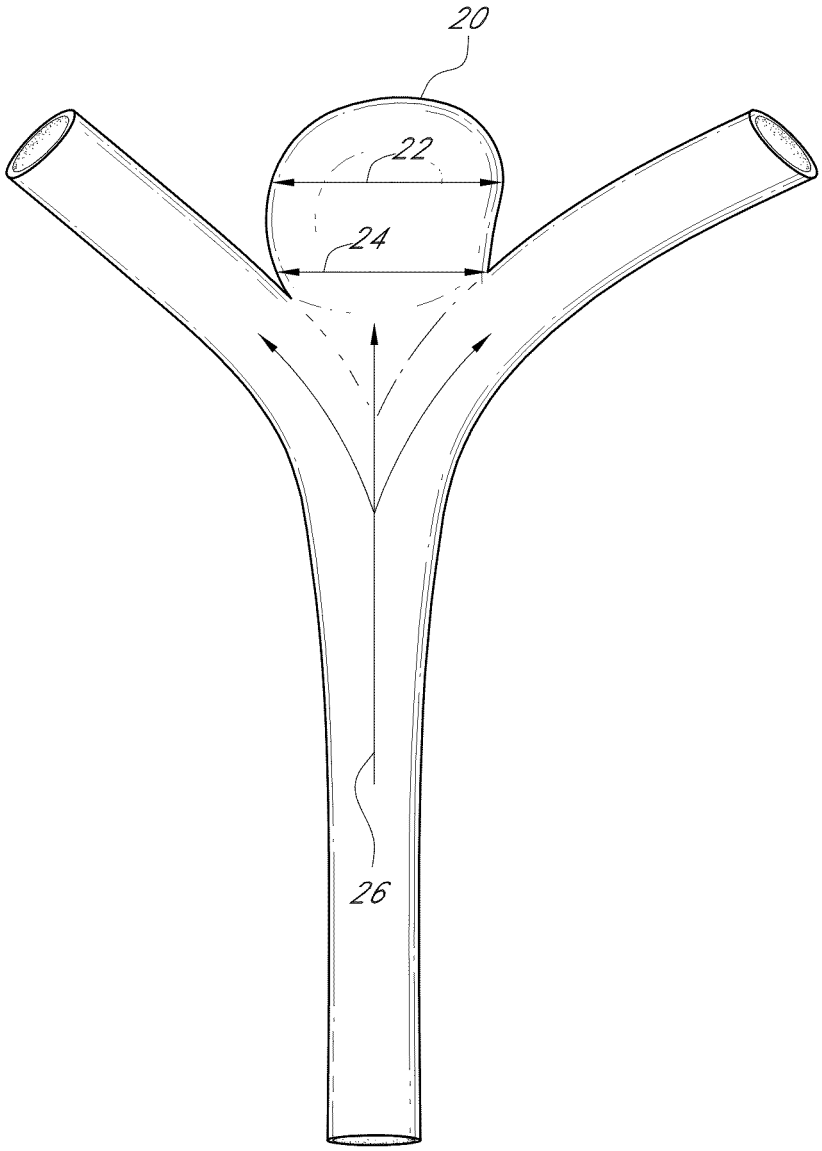

FIG. 2

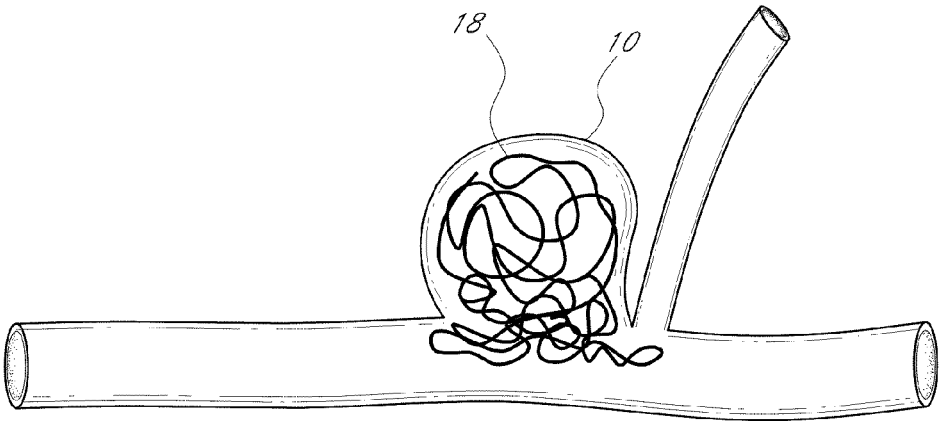

FIG. 3A

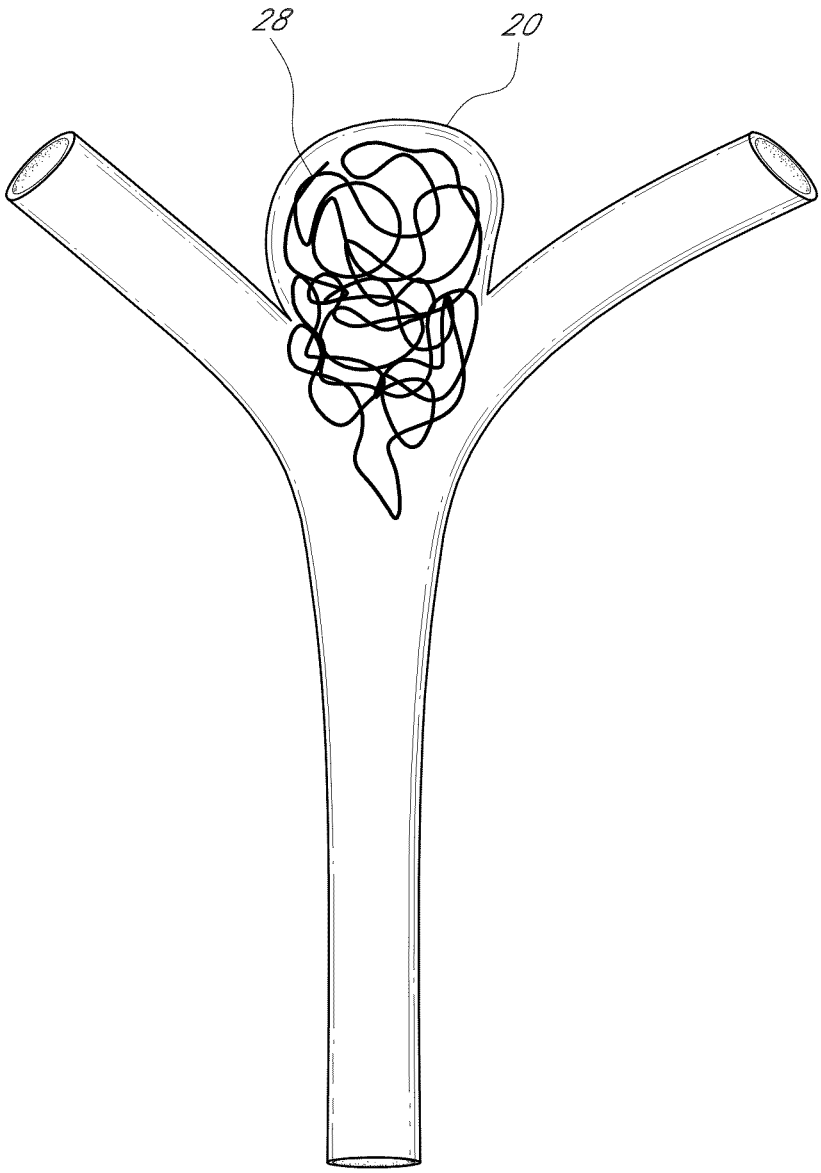

FIG. 3B

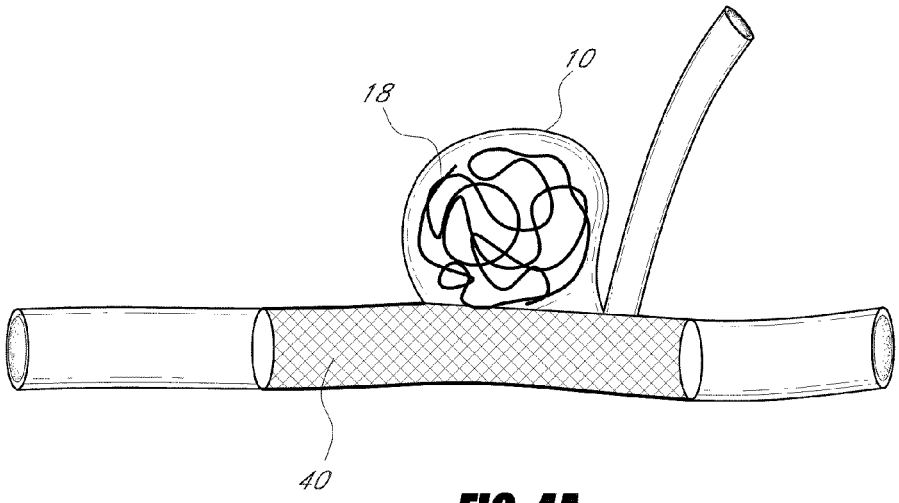

FIG. 4A

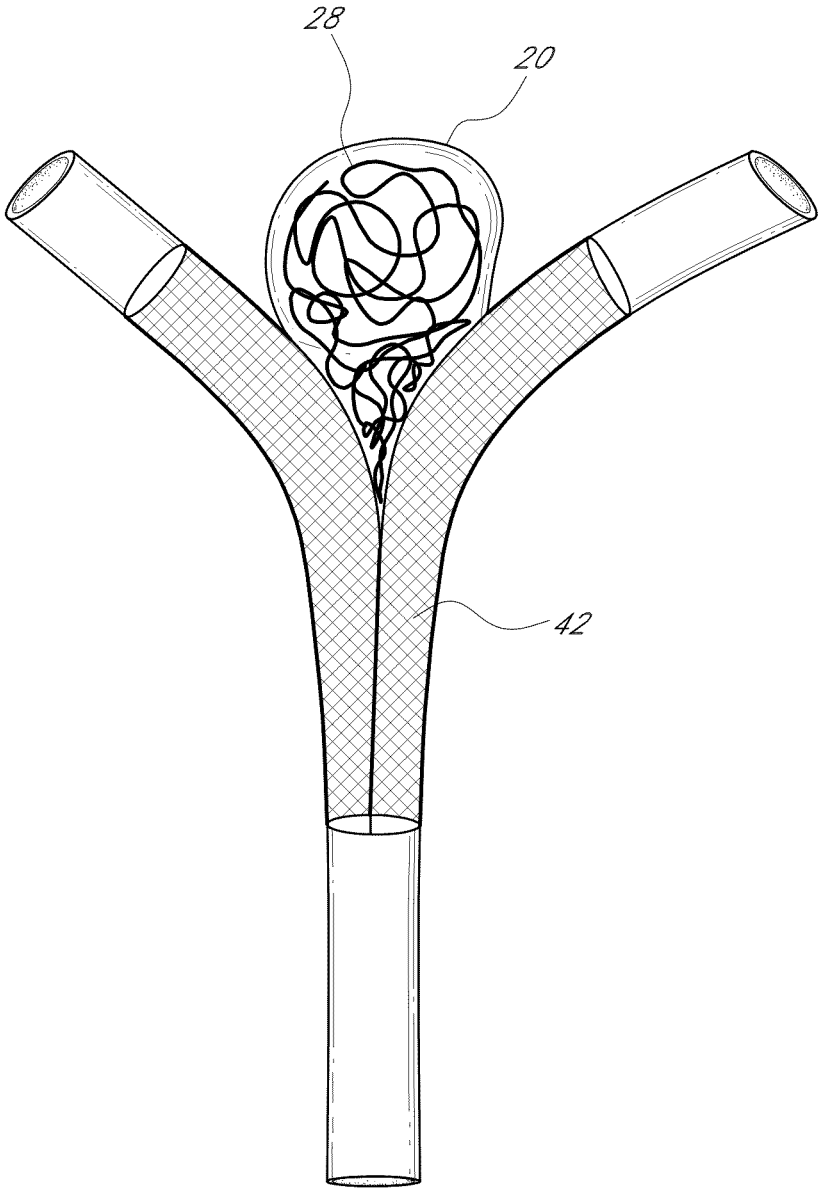

FIG. 4B

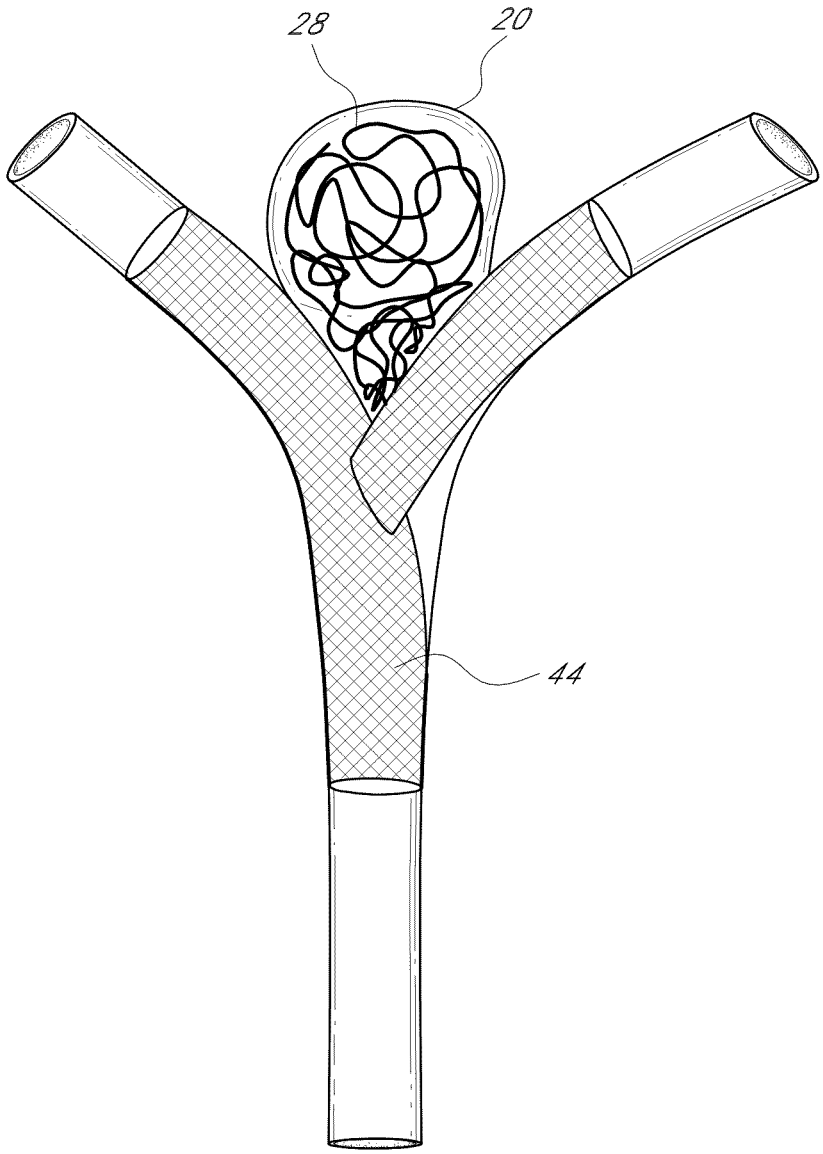

FIG. 4C

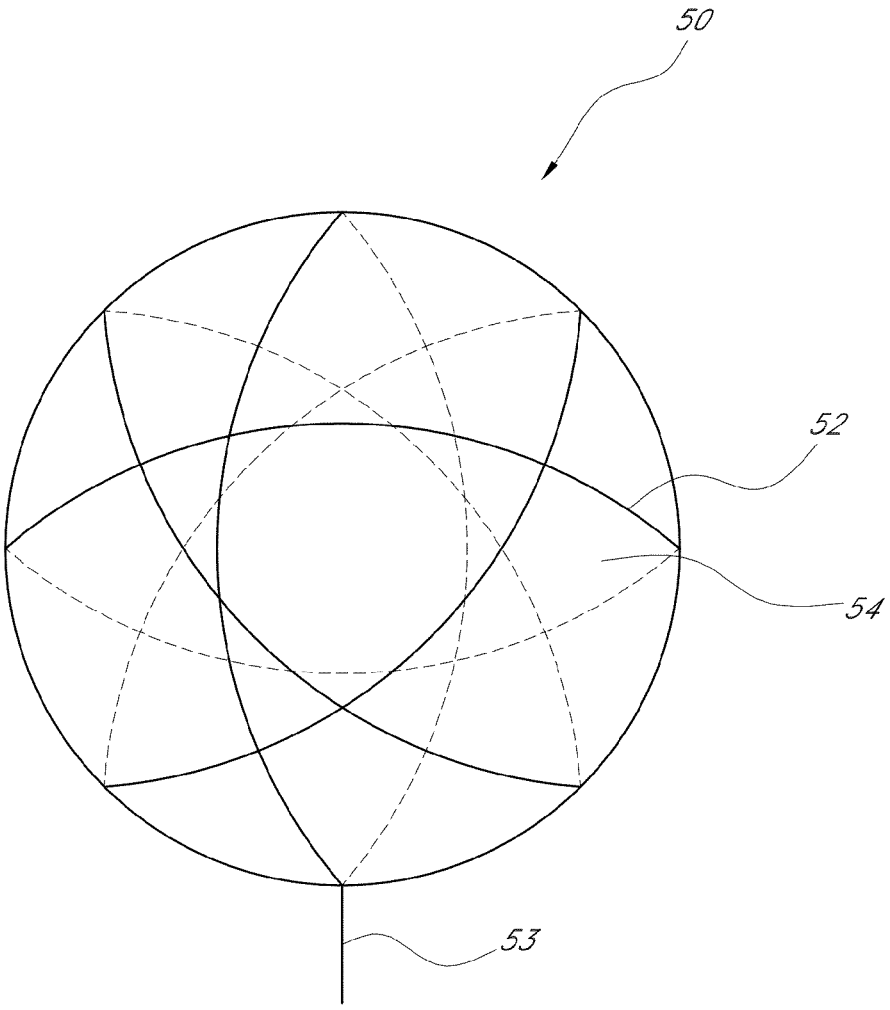

FIG. 5

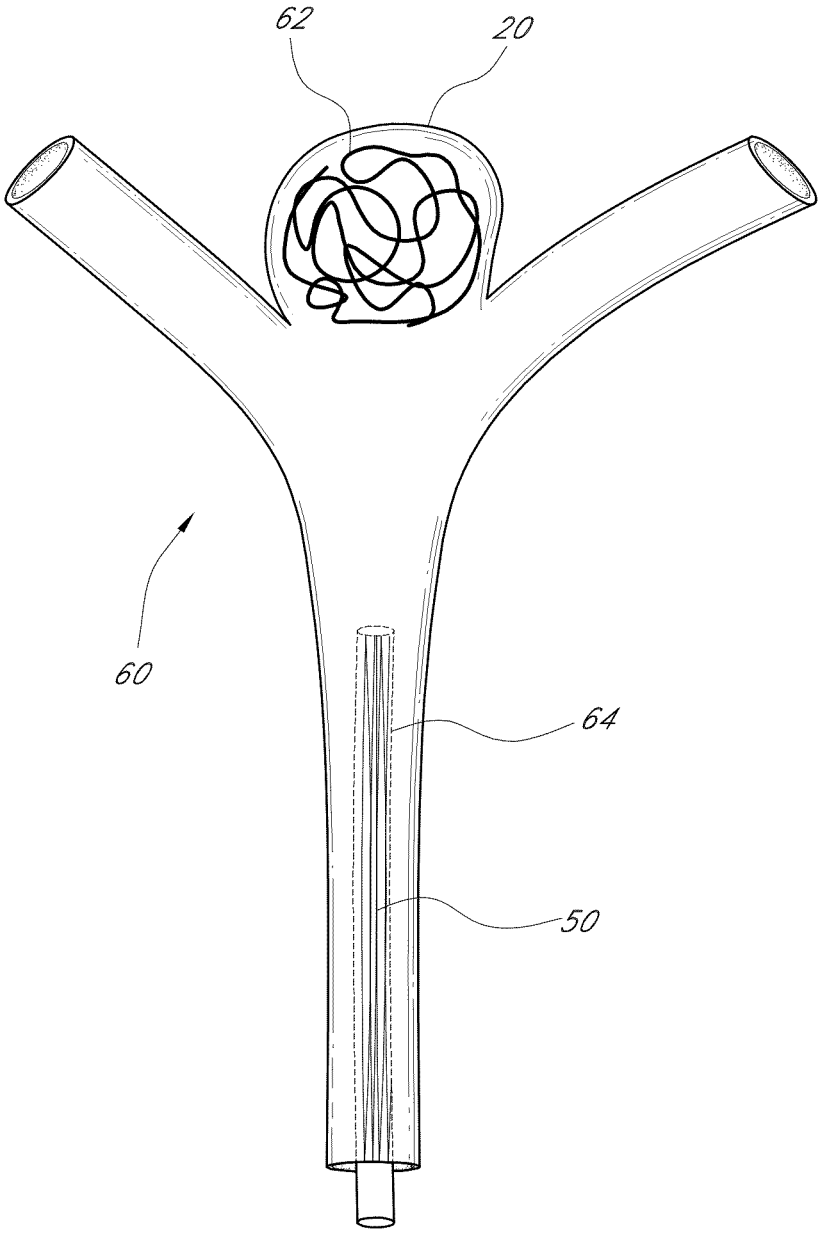

FIG. 6A

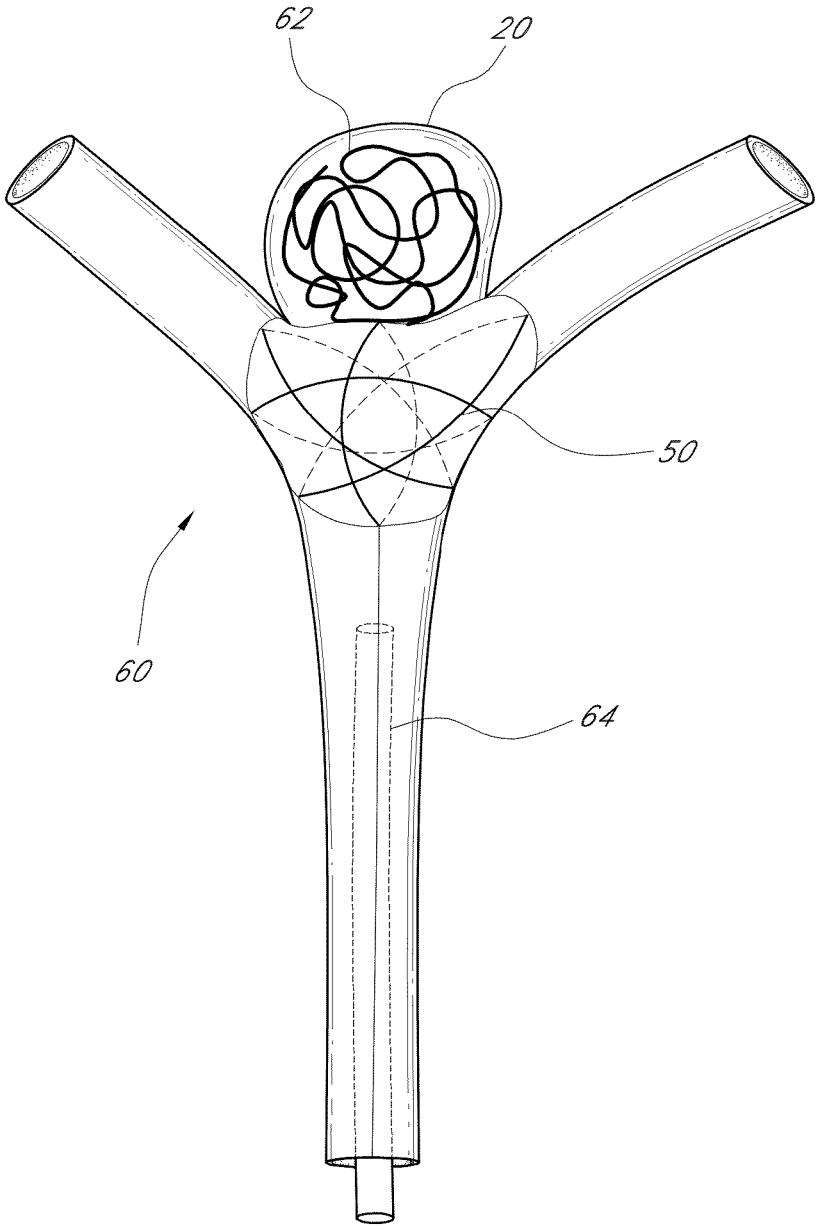

FIG. 6B

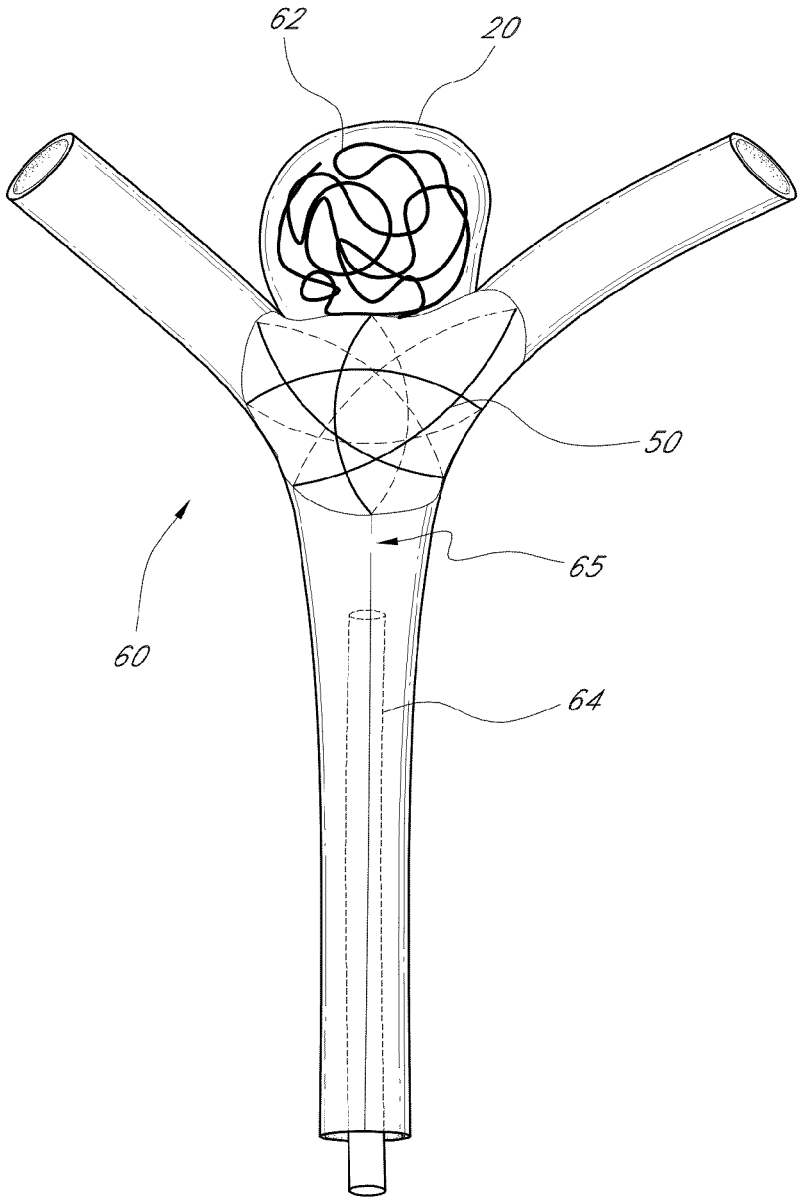

FIG. 6C

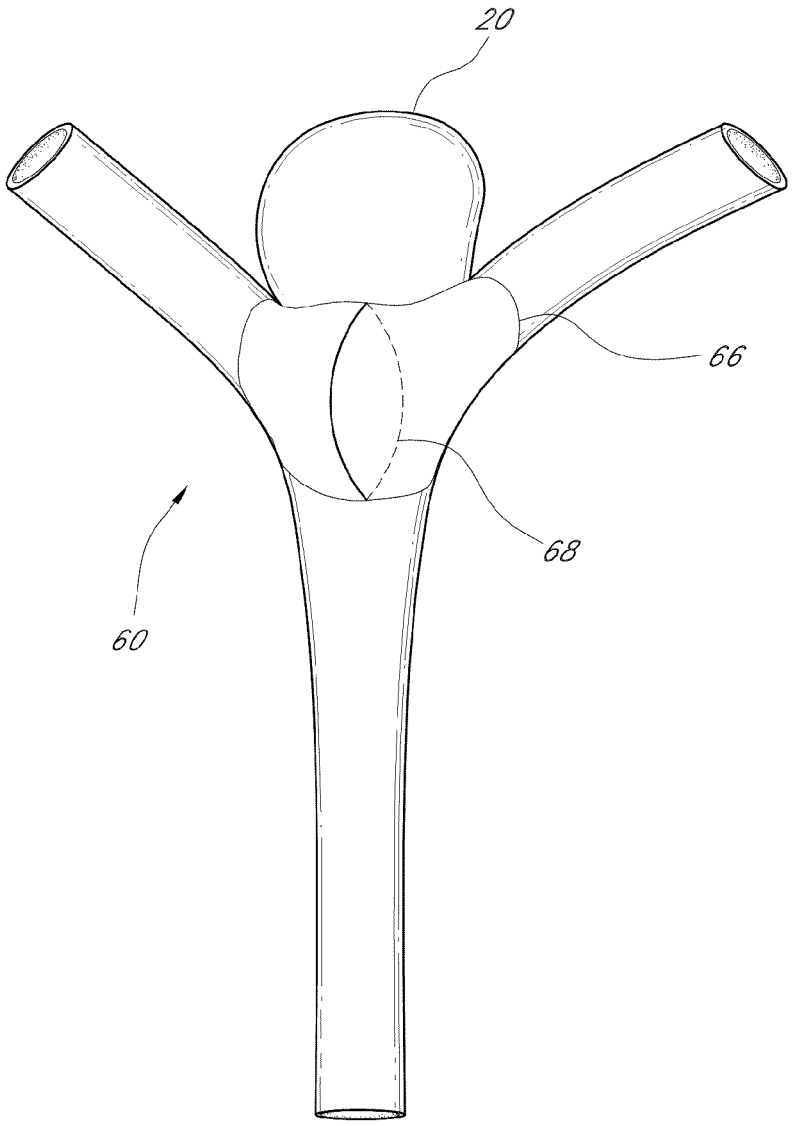

FIG. 7A

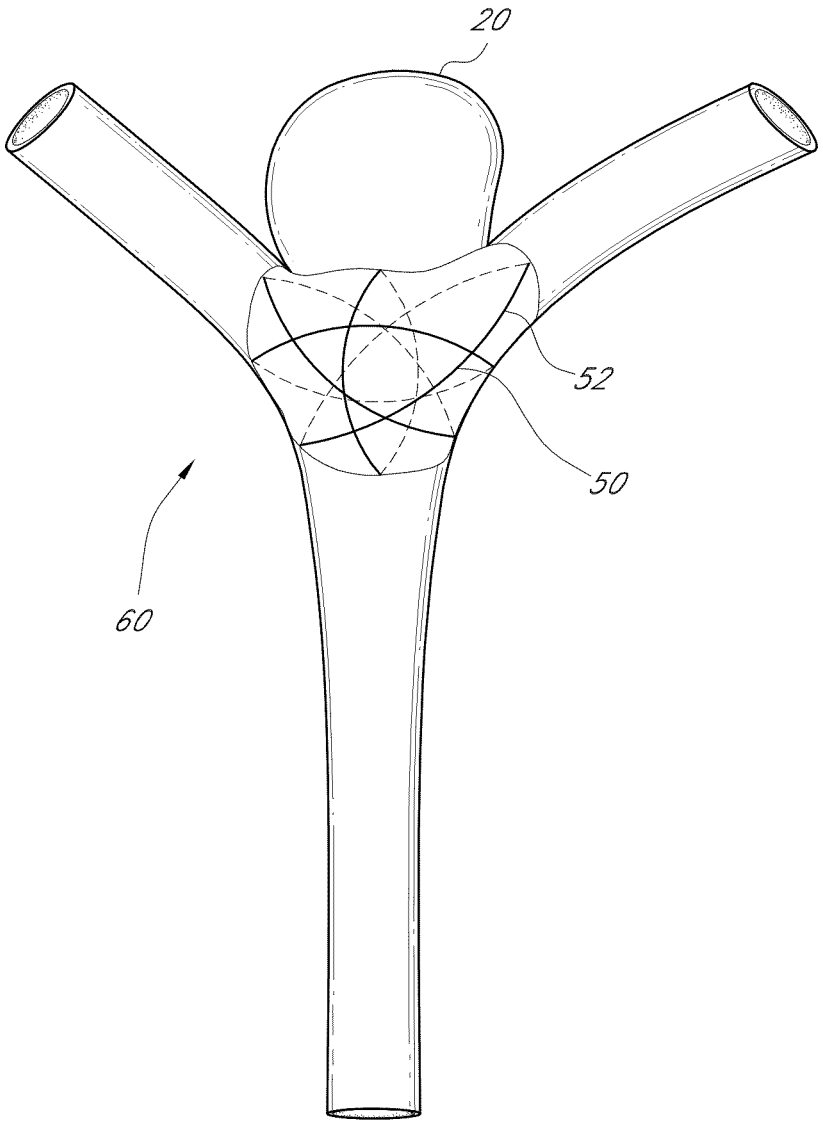

FIG. 7B

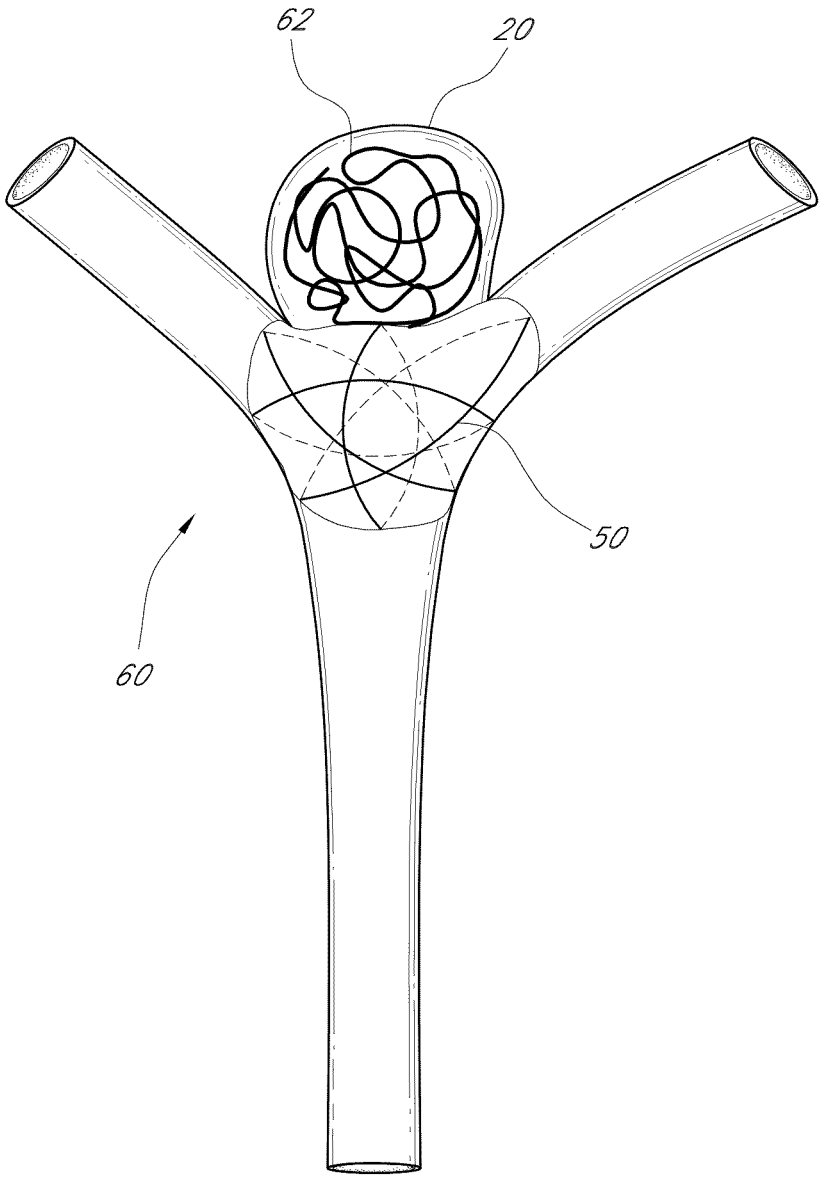

FIG. 7C

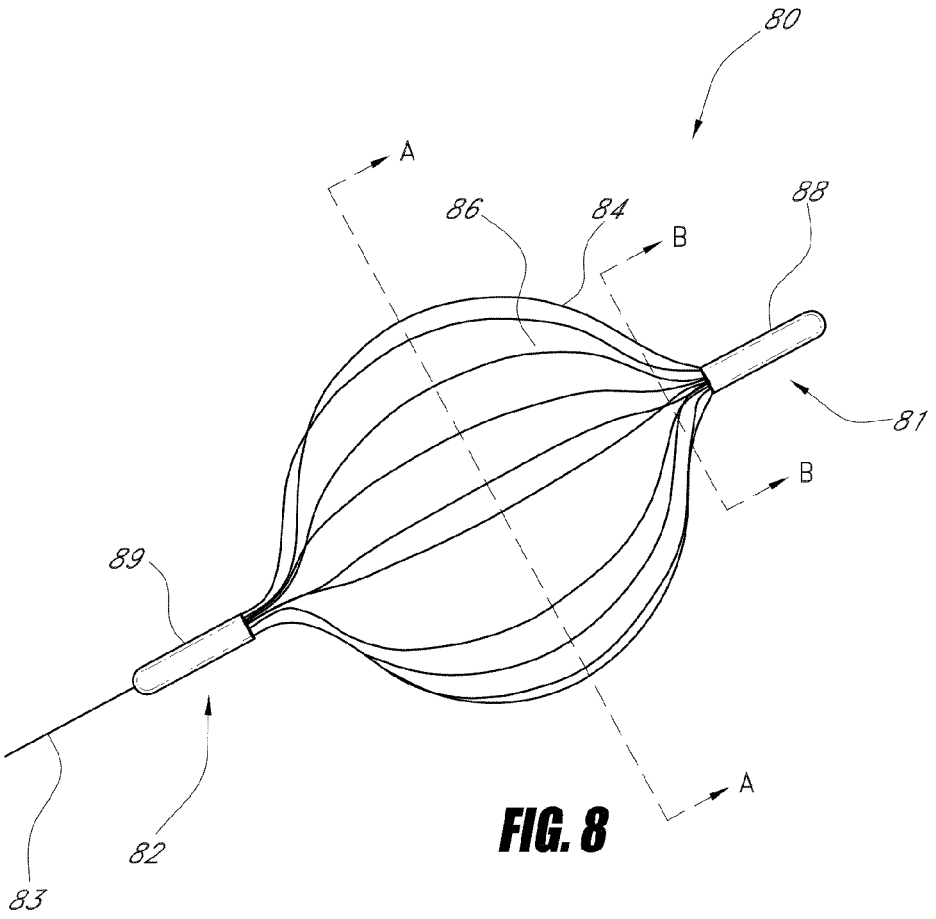

FIG. 8

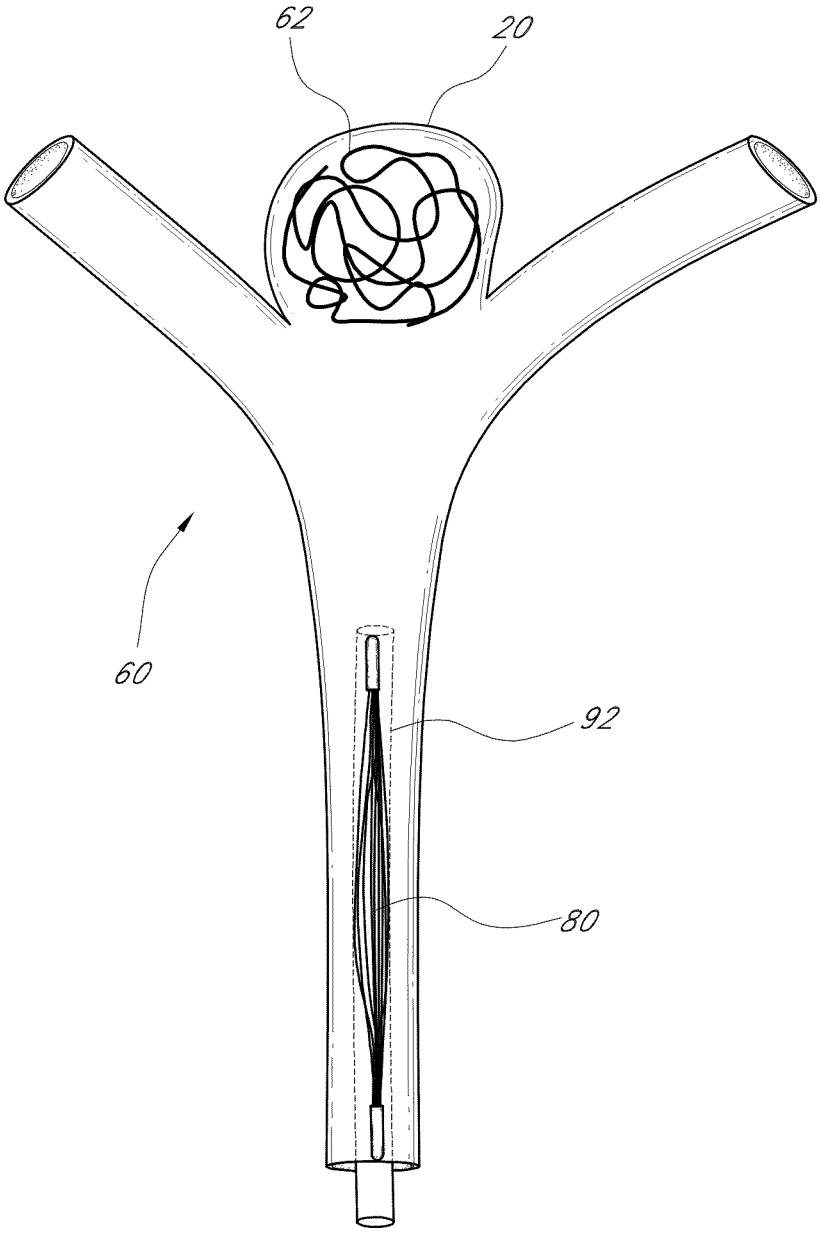

FIG. 9A

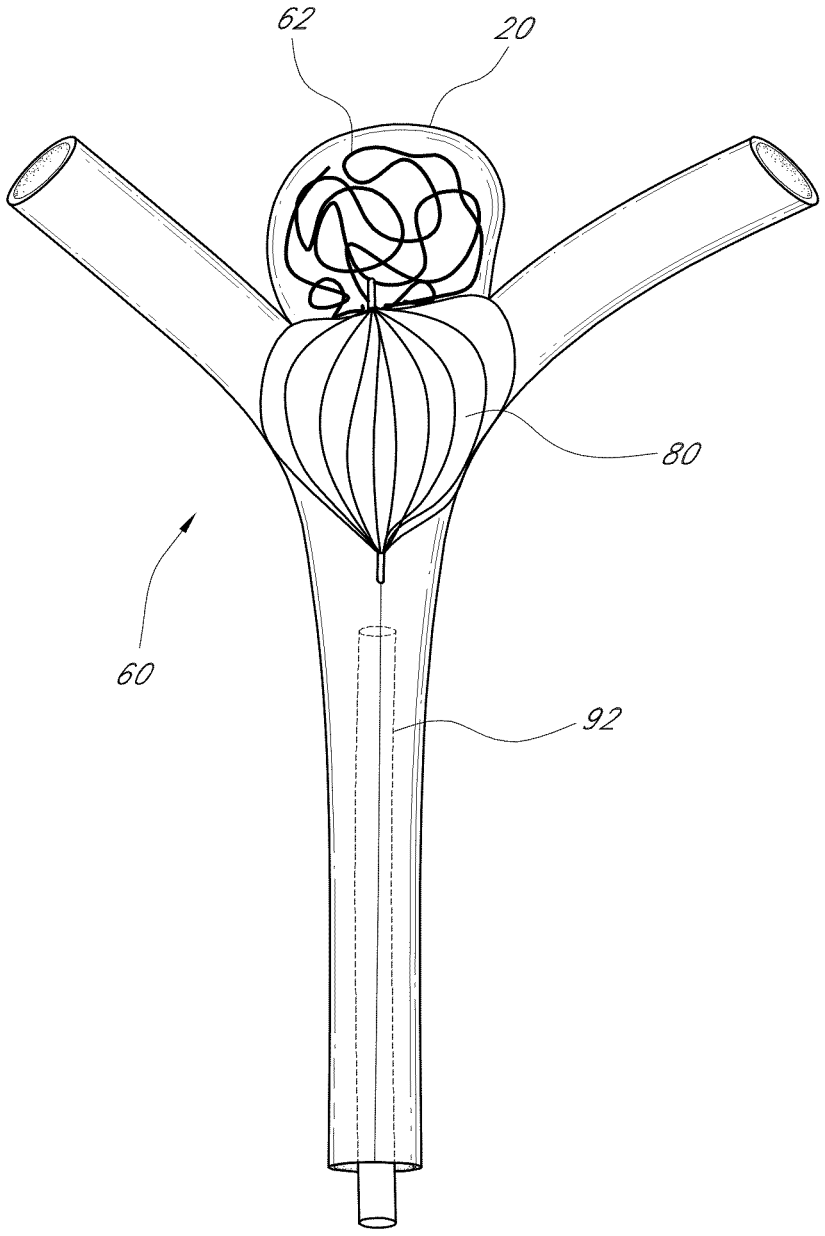

FIG. 9B

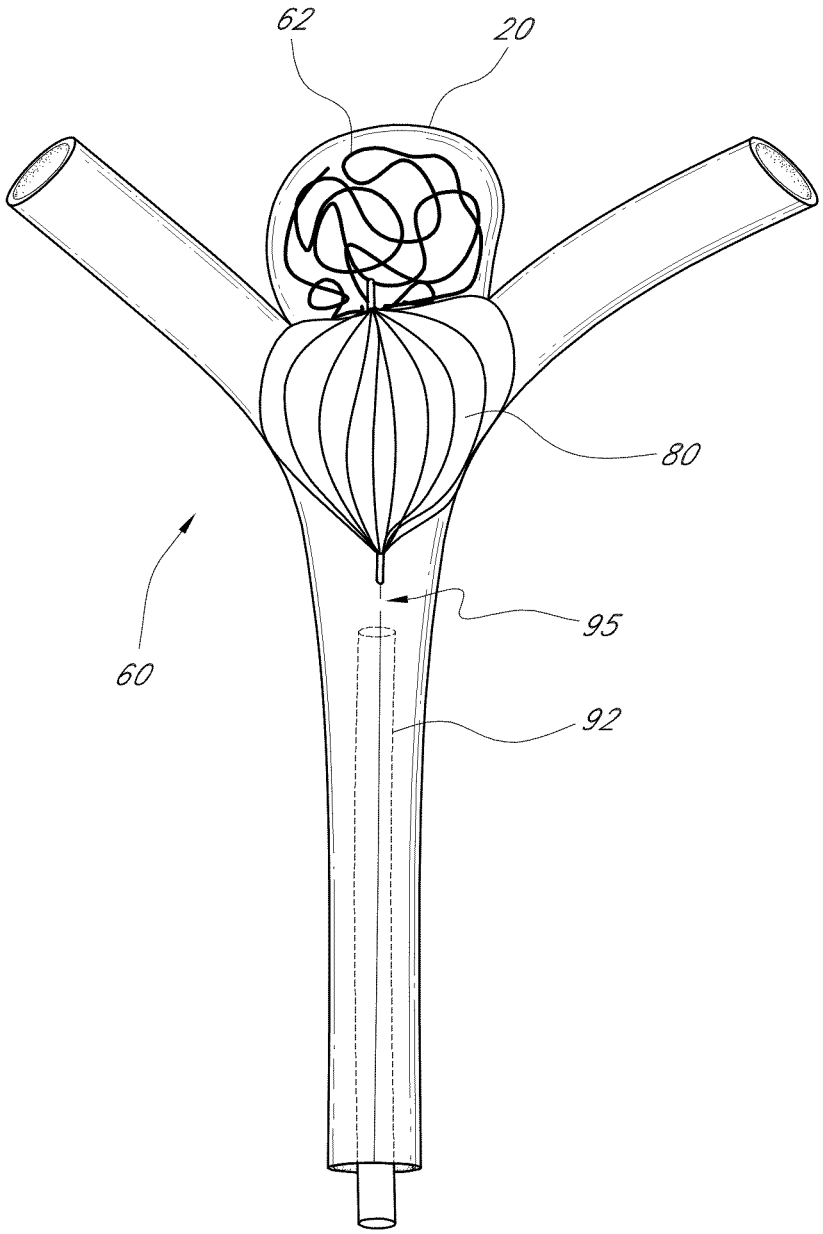

FIG. 9C

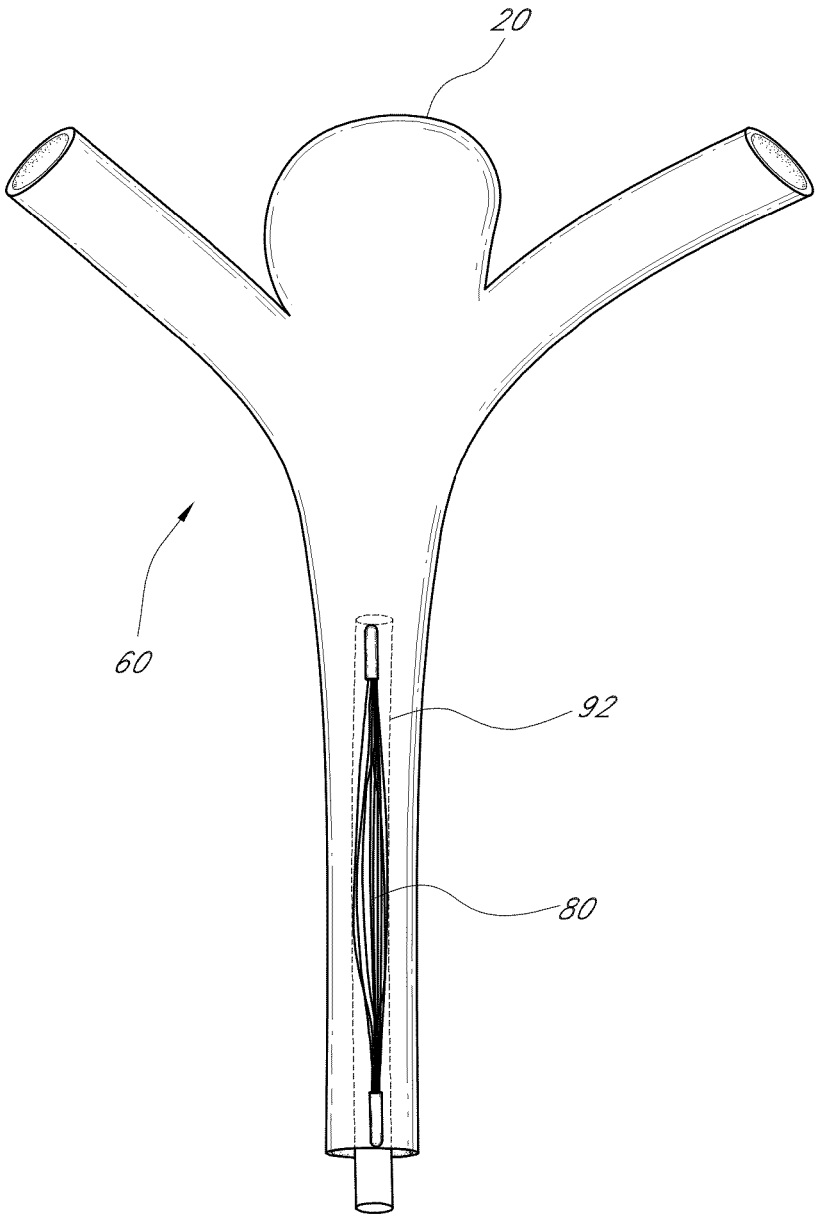

FIG. 10A

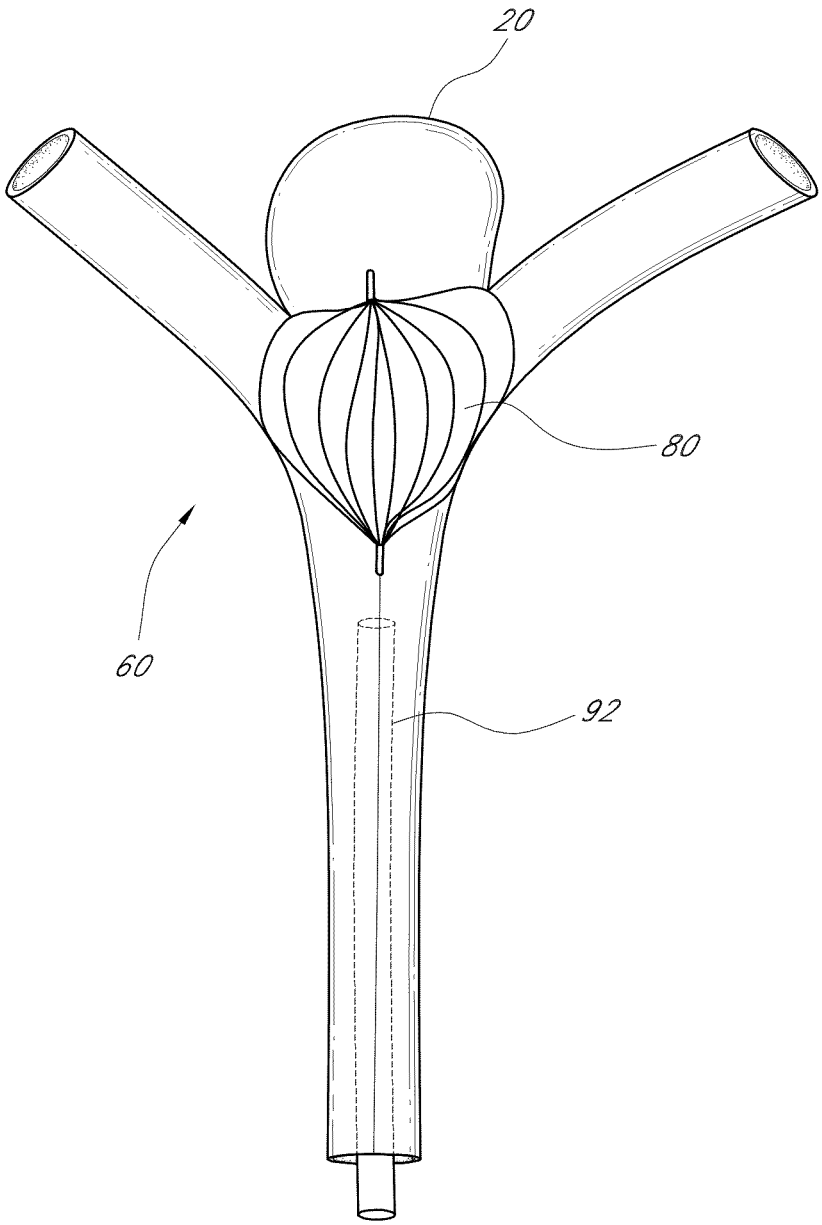

FIG. 10B

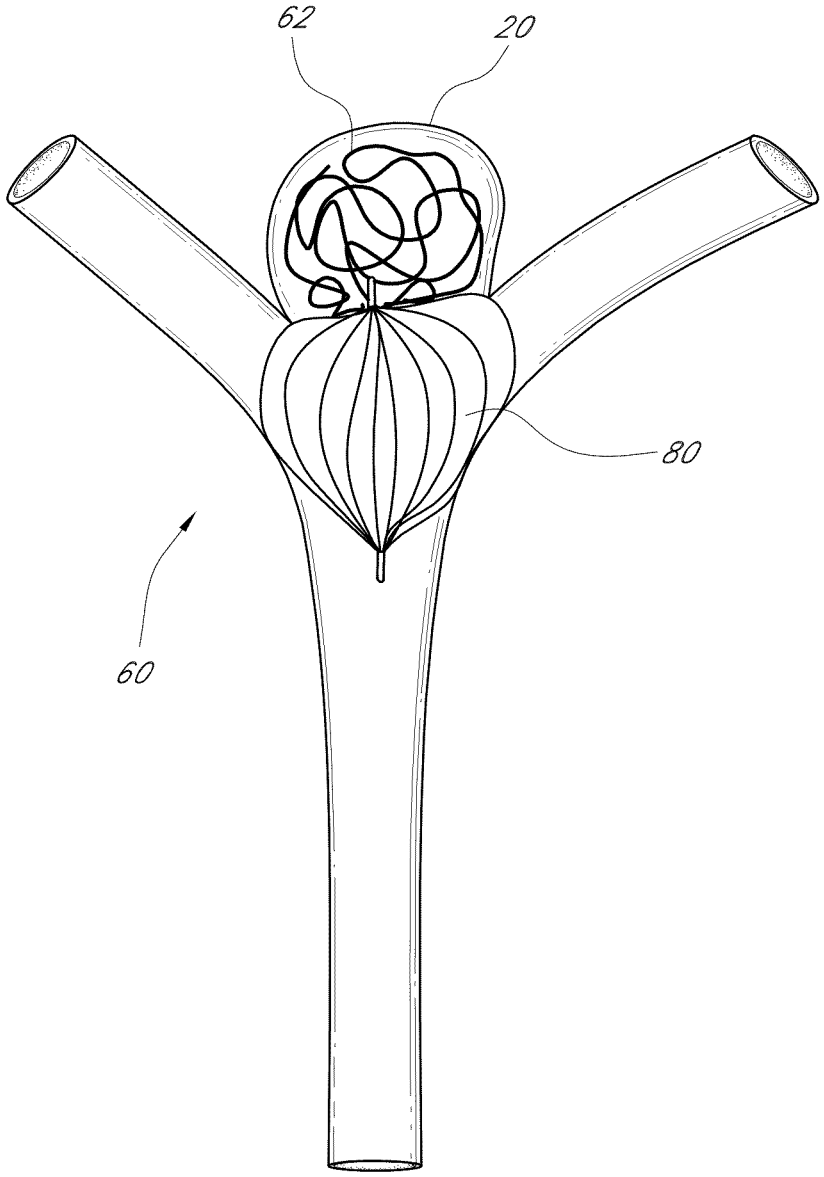

FIG. 10C

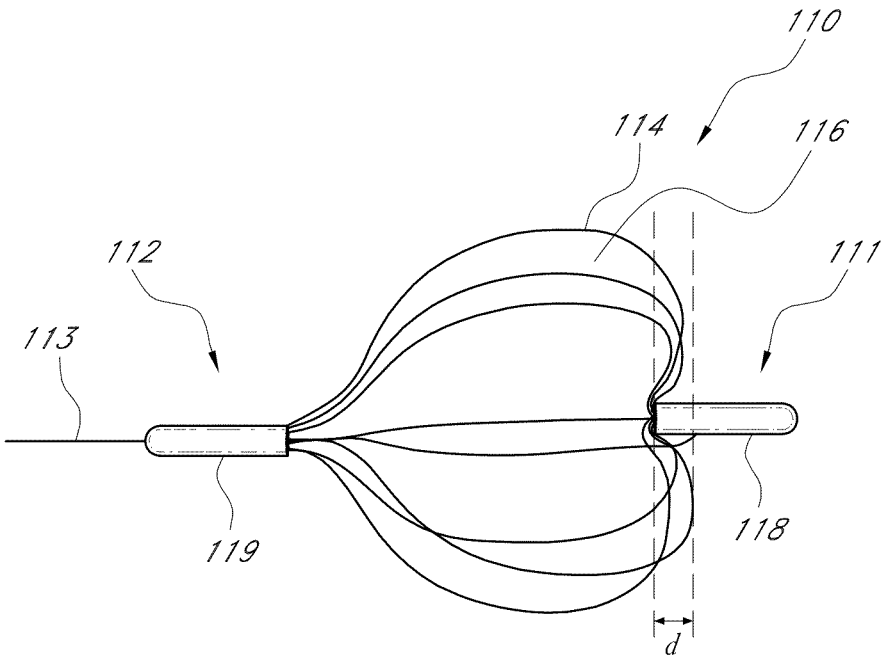

FIG. 11

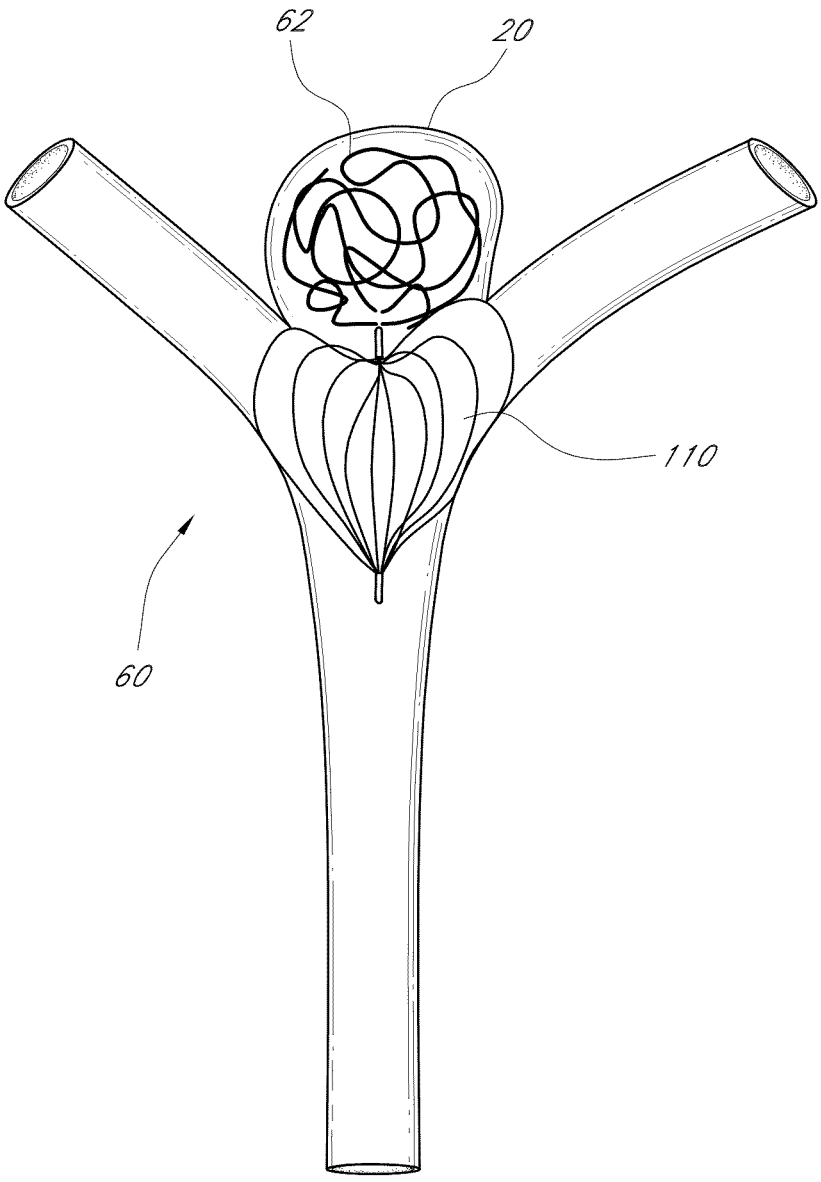

FIG. 12

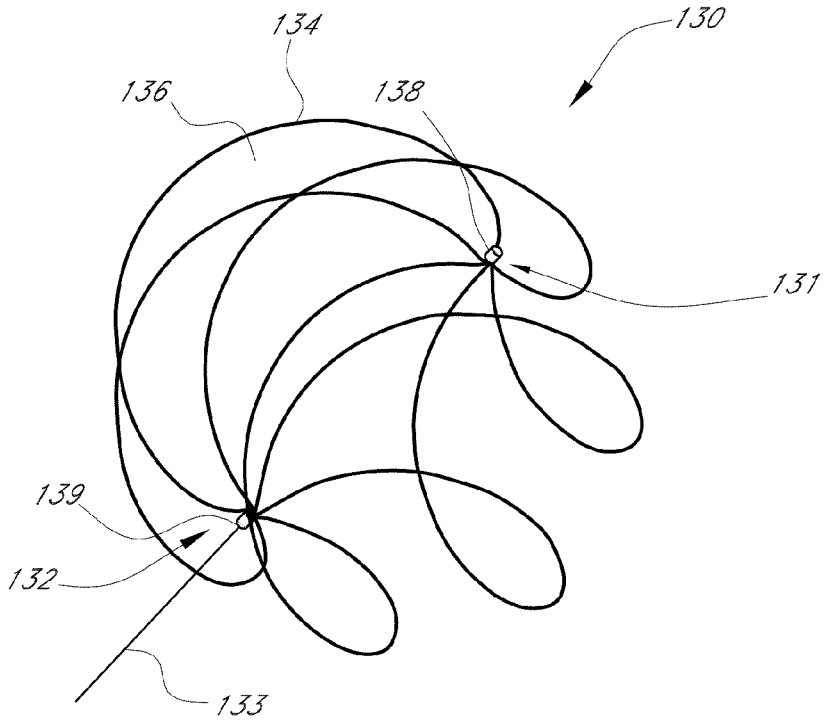

FIG. 13

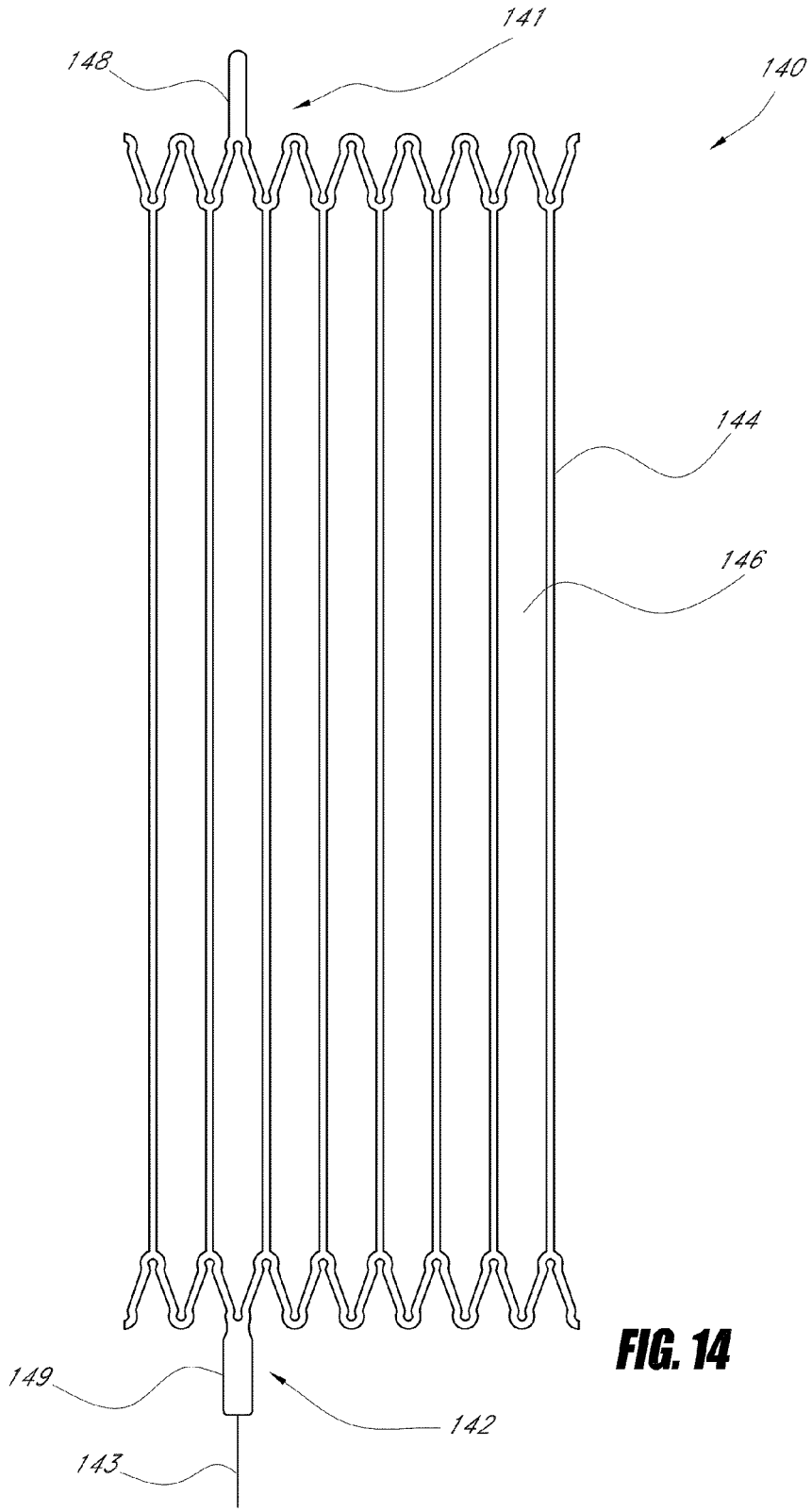

FIG. 14

VASCULAR REMODELING DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application No. 61/082,579, filed Jul. 22, 2008, which is incorporated herein by reference in its entirety.

BACKGROUND

1. Field

The present application generally relates to vascular remodeling devices and to the manner of their positioning in vessels, and, more particularly, to generally spherical remodeling devices and to the matter of their positioning at the junction of neurovascular bifurcations having an aneurysm.

2. Description of Related Art

Neurovascular or cerebral aneurysms affect about 5% of the population. Aneurysms may be located, for example, along arterial side walls (e.g., the aneurysm **10** illustrated in FIG. **1**) and at arterial bifurcations (e.g., the aneurysm **20** illustrated in FIG. **2**). The direction of fluid flow is generally indicated by the arrows **16**, **26**. The aneurysms **10**, **20** each have a fundus **12**, **22**, a neck **14**, **24**, and a fundus-to-neck ratio or "neck ratio." If the neck ratio is greater than 2 to 1 or if the neck **14**, **24** is less than 4 mm, the aneurysm **10**, may be treated with embolization coils alone because the coils will generally constrain themselves within the aneurysm **10**, **20** without herniating into parent vessels. If the neck ratio is less than 2 to 1 or if the neck **14**, **24** is greater than 4 mm, the aneurysms **10**, **20** may be difficult to treat with embolization coils alone because the coils may be prone to herniating into parent vessels, as illustrated in FIGS. **3**A and **3**B. Herniation of coils may cause arterial occlusion, stroke, and/or death. Compared to the bifurcation illustrated in FIG. **2**, the efferent vessels of the bifurcation may be at substantially different angles, have substantially different sizes, and/or be a different quantity (e.g., three or more). Compared to the bifurcation illustrated in FIG. **2**, the aneurysm **20** of the bifurcation may be offset with respect to the junction (e.g., having a neck substantially open to one efferent vessel), tilted with respect to a plane created by the vessels (e.g., into or out of the page), etc. Each of these would still be accurately characterized as a "bifurcation" herein.

In order to inhibit such herniation, tubular neck remodeling devices, for example Neuroform™, available from Boston Scientific, and Enterprise™, available from Cordis Neurovascular, may be used to keep coils or other materials within the fundus of the aneurysm and out of the vessels. Tubular remodeling devices generally consist of a braided wire or cut metallic stent or stents covering the neck of the aneurysm so that materials introduced into the fundus of the aneurysm do not herniate out of the aneurysm. As illustrated in FIG. **4**A, tubular remodeling devices **40** are generally useful for side wall aneurysms **10**. As illustrated in FIGS. **4**B and **4**C, tubular remodeling devices **42**, **44** are generally less useful for aneurysms **20** at bifurcations, for example because shaping the remodeling devices to preserve blood flow through the afferent and efferent vessels while also inhibiting herniation of coils **28** out of the aneurysm **20** can be difficult.

SUMMARY

In some embodiments described herein, a generally spherical vascular remodeling device is provided. The device is permanently positionable at a junction of afferent and efferent vessels of a bifurcation (e.g., a neurovascular bifurcation) having an aneurysm having a fundus and a neck. Positioning may comprise deployment from a catheter and mechanical or electrolytic release from the catheter. After positioning the device at the junction, the device can lock into place across the arterial ostia and the neck of the aneurysm, substantially conforming to the shape of the junction. After positioning the device at the junction, the device acts as a scaffolding to inhibit or prevent herniation or prolapse of objects such as embolization coils and thrombi out of the neck of the aneurysm. Embolic material may be inserted in the fundus of the aneurysm before or after positioning the device. After positioning the device at the junction, the device permits perfusion of fluid (e.g., blood) to the efferent vessels. The device may have a first end, a second end substantially opposite to the first end, and a plurality of filaments extending between and coupled at the first end and the second end. Certain such devices may be football shaped, pumpkin shaped, or twisted. The device may comprise a plurality of loops (e.g., circular loops) forming a generally spherical shape, each loop comprising a self-expanding and/or a shape-memory material (e.g., comprising Nitinol, CoCr alloy, etc.). Radiopaque markers may be placed at one or both ends of the device and/or at least one of the loops or filaments may comprise a radiopaque material (e.g., platinum).

In certain embodiments, a method of treating an aneurysm at a bifurcation having an afferent vessel and efferent vessels having a junction is provided. The aneurysm has a neck and a fundus. The method comprises advancing a catheter proximate to the junction of the bifurcation. The catheter at least partially contains a generally spherical vascular remodeling device in a compressed state. The method further comprises positioning the device at the junction of the bifurcation. The device acts as a scaffolding to inhibit herniation of objects out of the nexk of the aneurysm. The device permits perfusion of fluid to the efferent vessels.

In certain embodiments, a generally spherical remodeling device comprises a first end, a second end substantially opposite to the first end, and a plurality of filaments extending between the first end and the second end and coupled at the first end and the second end. The device is configured to be positioned at a junction of a neurovascular bifurcation comprising at least one afferent vessel, efferent vessels, and an aneurysm having a neck. The device is configured to act as a scaffolding to inhibit herniation of objects out of the neck of the aneurysm. The device is configured to permit perfusion of fluid to the efferent vessels. In certain embodiments, the filaments extend continuously in a direction along the longitudinal axis from the first end to the second end, with no longitudinal reversal of direction.

In certain embodiments, a remodeling device comprises a plurality of loops forming a generally spherical shape. The device is configured to be positioned at a junction of a neurovascular bifurcation having an aneurysm. The device is configured to act as a scaffolding to inhibit matter from herniating out of the aneurysm. The device is configured to permit perfusion of blood to efferent vessels of the bifurcation.

For purposes of summarizing the invention and the advantages achieved over the prior art, certain objects and advantages of the invention are described herein. Of course, it is to be understood that not necessarily all such objects or advantages need to be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group

of advantages as taught or suggested herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments will become readily apparent to those skilled in the art from the following detailed description having reference to the attached figures, the invention not being limited to any particular disclosed embodiment(s).

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects, and advantages of the present disclosure are described with reference to the drawings of certain embodiments, which are intended to illustrate certain embodiments and not to limit the invention.

FIG. **1** illustrates an example embodiment of a side wall aneurysm.

FIG. **2** illustrates an example embodiment of a bifurcation having an aneurysm.

FIG. **3**A illustrates an example embodiment of a side wall aneurysm with herniating embolization coils.

FIG. **3**B illustrates an example embodiment of a bifurcation having an aneurysm with herniating embolization coils.

FIG. **4**A illustrates an example embodiment of a side wall aneurysm treated with embolization coils and a tubular remodeling device.

FIGS. **4**B and **4**C illustrates example embodiments of a bifurcation having an aneurysm treated with embolization coils and tubular remodeling devices.

FIG. **5** illustrates an example embodiment of a generally spherical vascular remodeling device.

FIGS. **6**A-**6**C illustrate an example embodiment of a method for treating an aneurysm using the device of FIG. **5**.

FIGS. **7**A-**7**C illustrate another example embodiment of a method for treating an aneurysm using the device of FIG. **5**.

FIG. **8** illustrates another example embodiment of a generally spherical vascular remodeling device.

FIGS. **9**A-**9**C illustrate an example embodiment of a method for treating an aneurysm using the device of FIG. **8**.

FIGS. **10**A-**10**C illustrate another example embodiment of a method for treating an aneurysm using the device of FIG. **8**.

FIG. **11** illustrates yet another example embodiment of a generally spherical vascular remodeling device.

FIG. **12** illustrates an example embodiment of treating an aneurysm using the device of FIG. **11**.

FIG. **13** illustrates still another example embodiment of a generally spherical vascular remodeling device.

FIG. **14** illustrates an example embodiment of a generally spherical vascular remodeling device at a stage of an example manufacturing process.

DETAILED DESCRIPTION

Although certain embodiments and examples are described below, those of skill in the art will appreciate that the invention extends beyond the specifically disclosed embodiments and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the invention herein disclosed should not be limited by any particular embodiments described below.

FIG. **5** illustrates an example embodiment of a generally spherical vascular remodeling device **50**. It will be appreciated that the device **50** may be more compliant than the vasculature in which it is deployed such that it may be somewhat misshapen (e.g., non-spherical, for example as illustrated in FIG. **6**B) after being deployed, and that the phrase "generally spherical" describes the shape of the device **50** when in an expanded (e.g., fully expanded) state. Additionally, the phrase "generally spherical" distinguishes the device **50**, which is generally uniform in each dimension in an expanded state, from tubular stents having a small radial dimension and a large longitudinal dimension in an expanded state. In some embodiments of a generally spherical device, an outer periphery of the device has a shape that deviates by between about 10% and about 25% from an outer periphery of a mathematically perfect sphere. In some embodiments, the device **50** has a length and a width that are within less than about 33% of each other (e.g., having a length of 6 mm and a width of 8 mm, having a length of 6 mm and a width of 8 mm). Embodiments in which the width is greater than the length may be advantageous due to a difference in porosity at a midpoint and an end proximate to an aneurysm. Embodiments in which the length is greater than the width may be advantageous for positioning a portion of the device **50** in a portion of the aneurysm **20** (e.g., to aid in embolization).

In the embodiment illustrated in FIG. **5**, the device **50** comprises a plurality of generally circular loops **52** coupled together. Coupling of the loops **52** may comprise adhering, welding, soldering, interlacing (e.g., some loops **52** being over or under other loops **52**), intertwining, meshing, combinations thereof, and the like. In the embodiment illustrated in FIG. **5**, the device **50** comprises a lead or tail **53**, which may be used for releasing and/or retracting the device **50** after deployment, as described herein. In some embodiments, the device **50** comprises a cut metallic sphere, a single filament, a plurality of non-circular filaments (e.g., arcuate segments), etc. In some embodiments, each loop **52** forms a plane and the intersections of the planes are substantially parallel (e.g., as illustrated in FIG. **7**A).

In some embodiments, at least some of the loops **52** or filaments comprise a self-expanding and/or a shape-memory material (e.g., comprising Nitinol, CoCr alloy, etc.), thereby causing the device **50** to be self-expanding under certain conditions (e.g., not restrained by a catheter). In some embodiments, at least one of the loops **52** comprises a different material than others of the loops **52** (e.g., some loops **52** comprising Nitinol and some loops **52** comprising Nitinol and platinum). In some embodiments, at least one of the loops **52** comprises a radiopaque material (e.g., platinum). In certain such embodiments, an even number of loops **52** (e.g., two, four, etc.) comprises a radiopaque material (e.g., platinum). In some embodiments, at least one of the loops **52** comprises a radiopaque material (e.g., platinum) at least partially wrapped (e.g., coiled) around a self-expanding material (e.g., Nitinol). In some embodiments, at least one of the loops **52** comprises a self-expanding material with a radiopaque core (e.g., Nitinol with a platinum core) or a radiopaque coating (e.g., Nitinol coated with platinum, tantalum, etc. by physical vapor deposition, chemical vapor deposition, plating, etc.). It will be appreciated that the amount and type of radiopaque material used may depend, inter alia, on price, desired level of radiopacity, mechanical properties of the radiopaque material, and corrosion properties of the radiopaque material. In certain embodiments, the loops **52** have a substantially circular or ovoid cross section (e.g., embodiments, in which the loops **52** comprise separate wires). In some embodiments, the loops **52** have a substantially rectangular or flat cross section (e.g., embodiments, in which the loops **52** comprise uncut portions of a metallic tube). Other shapes of loops **52** and combinations of shapes of loops **52** are also possible. In certain embodiments, the plurality of loops **52** comprises between about six and about twelve loops **52**. In certain embodiments, the plurality of loops **52** comprises at

least about six loops **52**, at least about eight loops **52**, or at least about twelve loops **52**. Other numbers of loops **52** are also possible.

In certain embodiments, the device **50** is configured to be positioned at a junction of a bifurcation (e.g., a neurovascular bifurcation) comprising at least one afferent vessel, efferent vessels, and an aneurysm having a fundus and a neck. For example, in some embodiments, the device **50** is suitably dimensioned to fit in a junction of a bifurcation (e.g., having a diameter between about 2 mm and about 12 mm, having a diameter between about 6 mm and about 8 mm, having a diameter less than about 12 mm, having a diameter greater than about 2 mm). For another example, in some embodiments, the device **50** is less rigid than a junction of a bifurcation (e.g., due to the number of loops **52**, the material of the loops **52**, the thickness of the loops **52**, the spacing of the loops **52**, the shape of the loops **52**, combinations thereof, and the like). In certain embodiments, the device **50** is configured to act as a scaffolding to inhibit or prevent herniation or prolapse of objects (e.g., embolization coils, thrombi, etc.) out of a neck of an aneurysm. For example, in some embodiments, the loops **52** are dense enough at the neck of the aneurysm that objects cannot pass. In certain embodiments, the device **50** is configured to permit perfusion of fluid (e.g., blood) to efferent vessels of a bifurcation. For example, in some embodiments, the device **50** is substantially devoid of a covering, mesh, or other material between the loops **52**, thereby allowing fluid to flow substantially unimpeded.

The device **50** comprises a plurality of perforations or cells **54** between the loops **52**. In certain embodiments, a percentage of the outer surface of the device **50** covered by the loops **52** is between about 25% and about 40%. In certain embodiments, a percentage of the outer surface of the device **50** covered by the cells **54** is between about 60% and about 75%. Other porosities are also possible. In some embodiments (e.g., in embodiments in which the device **50** comprises loops **52** that form a plane and in which the intersections of the planes are substantially parallel (e.g., as illustrated in FIG. **7**A)), porosity distally increases between a proximal end of the device **50** and an approximate midpoint and distally decreases between the approximate midpoint and a distal end of the device **50**. In some embodiments, the device **50** further comprises one or more radiopaque markers (e.g., comprising or at least partially covering a portion of a loop **52**, at a proximal end of the device **50**, at a distal end of the device **50**, etc.).

FIGS. **6**A-**6**C illustrate an example embodiment of a method for treating an aneurysm **20** using the device **50**. FIG. **6**A illustrates a confluence of afferent and efferent vessels or "junction" at a bifurcation **60** having an aneurysm **20**. In some embodiments, the vessels are neurovascular or cranial. The aneurysm **20** is illustrated with a plurality of embolization coils **62** having been inserted in the fundus **22** of the aneurysm **20**. It will be appreciated that the embolization coils **62** may be a single embolization coil or other embolic material. A catheter **64** (e.g., a microcatheter), at least partially containing a constricted or compressed device **50**, is also shown in the afferent vessel. The catheter **64** is small enough and flexible enough to be routed through the vasculature and situated proximate to the aneurysm **20**. In some embodiments, the embolization coils **62** are inserted in the fundus **22** of the aneurysm **20** using the catheter **64**. In some embodiments, the embolization coils **62** are inserted in the fundus **22** of the aneurysm **20** using a different catheter. In certain such embodiments, a guidewire may be used to guide both catheters.

FIG. **6**B illustrates the bifurcation **60** after the device **50** has been deployed from the catheter **64** (e.g., by being pushed out with a plunger, by retracting the catheter **64** while the device **50** remains stationary, etc.). After being deployed from the catheter **64**, the device **50** may expand. In some embodiments, the device **50** comprises a self-expanding and/or a shape-memory material that automatically expands towards an uncompressed state or does so upon the application of warm fluid (e.g., saline). The device **50** may substantially conform to the shape of the junction of the bifurcation **60** (e.g., not substantially including portions extending into the afferent and efferent vessels) and locks into place across the ostia of the afferent and efferent vessels and the neck **24** of the aneurysm **20**. The device **50** at least partially covers the neck **24** of the aneurysm **20** as well as the afferent and efferent vessels, but does not need to divert flow. The device **50** acts as a scaffolding to inhibit or prevent herniation or prolapse of objects such as the embolization coils **62** and/or thrombi out of the aneurysm **20**. The device **50** also allows perfusion of fluid (e.g., blood) from the afferent vessel(s) to the efferent vessel(s).

FIG. **6**C illustrates the bifurcation **60** after the device **50** has been released from the catheter **64**. In some embodiments, the device **50** is released mechanically (e.g., by a release mechanism). In some embodiments, the device **50** is released electrolytically (e.g., by applying a small current until a portion of the tail **53** proximal to the device **50** corrodes away, as illustrated by the gap **65**). The catheter **64** is then withdrawn from the bifurcation **60**, thereby leaving or permanently positioning the device **50** at the junction of the bifurcation **60**.

It will be appreciated that the term "permanently" does not mean that the device **50** is impossible to remove at a later time. In some embodiments, the device **50** may be retracted into the catheter **64** after being deployed from the catheter **64** (e.g., by pulling on the tail **53**). The device **50** may then be deployed, for example at a new angle, at a new rotational position, more proximal or distal to an afferent vessel and/or an efferent vessel, etc. For example, although the device **50** expands towards an uncompressed state after deployment, the resulting shape of the device **50** at the junction of the bifurcation **60** may vary depending on the details of the deployment from the catheter **64** because the device **50** adapts to the shape of the anatomy (e.g., due to the size, shape, number, etc. of the loops **52**). Once the user is satisfied with properties of the device **50** (e.g., position, tilt, rotation, shape, interaction with the vessels, etc.), the device **50** may be released as described herein.

Combinations of the steps described above are also possible. In some embodiments, the embolization coils **62** may be inserted in the fundus **22** of the aneurysm **20** after the device **50** has been deployed from the catheter **64** (e.g., using the catheter **64** to insert the embolization coils **62**). In some embodiments, the embolization coils **62** may be inserted in the fundus **22** of the aneurysm **20** after the device **50** has been released from the catheter **64** (e.g., using the catheter **64** to insert the embolization coils **62**).

FIGS. **7**A-**7**C illustrate another example embodiment of a method for treating an aneurysm **20** using the device **50**. In the method described with respect to FIGS. **6**A-**6**C, the device **50** was pre-assembled outside of the vasculature prior to positioning. By contrast, in the method described with respect to FIGS. **7**A-**7**C, the device **50** is introduced piecemeal and is constructed within the patient at the bifurcation **60**. FIG. **7**A illustrates a first loop **66** and a second loop **68** positioned across the neck **24** of the aneurysm **20** and the ostia of the afferent and efferent vessels. In some embodiments, the first loop **66** is positioned and the second loop **68** is then positioned inside the first loop **66**. In some embodiments, a plane

defined by the positioned first loop **66** is substantially perpendicular to the plane of the neck **24** of the aneurysm **20** and a plane defined by the positioned second loop **68** is substantially perpendicular to the plane of the neck **24** of the aneurysm **20**. In certain embodiments, the first loop **66** and the second loop **68** are positioned via deployment from a same catheter. In certain embodiments, the first loop **66** is positioned via deployment from a first catheter, the second loop **68** is positioned via deployment from a second catheter, and so on. In some embodiments, the device **50** is not released from a catheter, but each loop **52** is released (e.g., mechanically, electrolytically, etc.) from a catheter. FIG. **7**B illustrates the device **50** after it has been fully constructed by positioning additional loops **52**. Embolization coils **62** may be inserted in the fundus **22** of the aneurysm **20** prior to construction of the device **50**, for example as described above with respect to FIG. **6**A, or after construction of the device **50** (e.g., as illustrated in FIG. **7**C).

Combinations of methods described herein are also possible. For example, a partially constructed device **50** may be positioned at the junction of the bifurcation **60**, and then the device **50** may be fully constructed at the junction of the bifurcation **60**. In certain such embodiments, a partially constructed device **50** having some missing loops **52** may allow better access to the aneurysm **20** for easier placement of the embolization coils **62**.

FIG. **8** illustrates another example embodiment of a generally spherical vascular remodeling device **80**. It will be appreciated that the device **80** may be more compliant than the vasculature in which it is deployed such that it may be somewhat misshapen (e.g., non-spherical, for example as illustrated in FIG. **9**B) after being deployed, and that the phrase "generally spherical" describes the shape of the device **80** when in an expanded (e.g., fully expanded) state. Additionally, the phrase "generally spherical" distinguishes the device **80**, which is generally uniform in each dimension in an expanded state, from tubular stents having a small radial dimension and a large longitudinal dimension in an expanded state. In some embodiments of a generally spherical device, an outer periphery of the device has a shape that deviates by between about 10% and about 25% from an outer periphery of a mathematically perfect sphere. In some embodiments, the device **80** has a length and a width that are within less than about 33% of each other (e.g., having a length of 6 mm and a width of 8 mm, having a length of 6 mm and a width of 8 mm). Embodiments in which the width is greater than the length may be advantageous due to a difference in porosity at a midpoint and an end proximate to an aneurysm. Embodiments in which the length is greater than the width may be advantageous for positioning a portion of the device **80** in a portion of the aneurysm **20** (e.g., to aid in embolization).

The device **80** comprises a first or distal end **81** and a second or proximal end **82** substantially opposite the first end **81**. The device **80** further comprises a plurality of filaments **84** extending between the first end **81** and the second end **82**. The first end **81** extends outwardly and the second end **82** extends outwardly to form a generally spherical (e.g., oval or oblong) shape similar to a football, a rugby ball, or a watermelon. In certain embodiments, the filaments **84** are coupled at the first end **81** and/or the second end **82** (e.g., by adhering, welding, soldering, combinations thereof, and the like). In the embodiment illustrated in FIG. **8**, the device **80** comprises a lead or tail **83**, which may be used for releasing and/or retracting the device **80** after deployment, as described herein. In certain embodiments, the device **80** comprises a cut metallic sphere, a single filament, etc.

In certain embodiments, the device **80** is configured to be positioned at a junction of a bifurcation (e.g., a neurovascular bifurcation) comprising at least one afferent vessel, efferent vessels, and an aneurysm having a fundus and a neck. For example, in some embodiments, the device **80** is suitably dimensioned to fit in a junction of a bifurcation (e.g., having a diameter between about 2 mm and about 12 mm, having a diameter between about 6 mm and about 8 mm, having a diameter less than about 12 mm, having a diameter greater than about 2 mm). For another example, in some embodiments, the device **80** is less rigid than a junction of a bifurcation (e.g., due to the number of filaments **84**, the material of the filaments **84**, the thickness of the filaments **84**, the spacing of the filaments **84**, the shape of the filaments **84**, combinations thereof, and the like). In certain embodiments, the device **80** is configured to act as a scaffolding to inhibit or prevent herniation or prolapse of objects (e.g., embolization coils, thrombi, etc.) out of a neck of an aneurysm. For example, in some embodiments, the filaments **84** are dense enough at the neck of the aneurysm that objects cannot pass. In certain embodiments, the device **80** is configured to permit perfusion of fluid (e.g., blood) to efferent vessels of a bifurcation. For example, in some embodiments, the device **80** is substantially devoid of a covering, mesh, or other material between the filaments **84**, thereby allowing fluid to flow substantially unimpeded.

In some embodiments, at least one of the filaments **84** comprises a self-expanding and/or a shape-memory material (e.g., comprising Nitinol, CoCr alloy, etc.), thereby causing the device **80** to be self-expanding under certain conditions (e.g., not restrained by a catheter). In some embodiments, at least one of the filaments **84** comprises a different material than others of the filaments **84** (e.g., some filaments **84** comprising Nitinol and some filaments **84** comprising Nitinol and platinum). In some embodiments, at least one of the filaments **84** comprises a radiopaque material (e.g., platinum). In certain such embodiments, an even number of filaments **84** (e.g., two, four, etc.) comprises a radiopaque material (e.g., platinum). In some embodiments, at least one of the filaments **84** comprises a radiopaque material (e.g., platinum) at least partially wrapped (e.g., coiled) around a self-expanding material (e.g., Nitinol). In some embodiments, at least one of the filaments **84** comprises a self-expanding material with a radiopaque core (e.g., Nitinol with a platinum core) or a radiopaque coating (e.g., Nitinol coated with platinum, tantalum, etc. by physical vapor deposition, chemical vapor deposition, plating, etc.). It will be appreciated that the amount and type of radiopaque material used may depend, inter alia, on price, desired level of radiopacity, mechanical properties of the radiopaque material, and corrosion properties of the radiopaque material. In certain embodiments, the filaments **84** have a substantially circular or ovoid cross section (e.g., embodiments, in which the filaments **84** comprise separate wires). In some embodiments, the filaments **84** have a substantially rectangular or flat cross section (e.g., embodiments, in which the filaments **84** comprise uncut portions of a metallic tube, as described below). Other shapes of filaments **84** and combinations of shapes of filaments **84** are also possible. In certain embodiments, the plurality of filaments **84** comprises between about six and about twelve filaments **84**. In certain embodiments, the plurality of filaments **84** comprises at least about six filaments **84**, at least about eight filaments **84**, or at least about twelve filaments **84**. Other numbers of filaments **84** are also possible.

The device **80** comprises a plurality of perforations or cells **86** between the filaments **84**. In certain embodiments, a percentage of the outer surface of the device **80** covered by the

filaments **84** is between about 25% and about 40%. In certain embodiments, a percentage of the outer surface of the device **80** covered by the cells **86** is between about 60% and about 75%. Other porosities are also possible. In some embodiments, porosity distally increases between the second end **82** and an approximate midpoint (e.g., approximately at the line A-A in FIG. **8**) and distally decreases between the approximate midpoint and the first end **81**. For example, cross-sections taken along the lines A-A and B-B in FIG. **8** each have the same number of filaments **84**, but at the cross-section A-A the filaments **84** are spaced further apart from each other than at the cross-section B-B. As an example, if the device comprises ten filaments **84** each having a thickness of 0.5 mm, the porosity at the cross-section A-A would be about 80% with an example circumference of about 25 mm:

$$100\% \times [1-(\approx 0.5 \text{ mm/filament} \times 10 \text{ filaments}/\approx 25 \text{ mm})] \approx 80\%$$

and the porosity at the cross-section B-B would be about 33% with an example circumference of about 7.5 mm:

$$100\% \times [1-(\approx 0.5 \text{ mm/filament} \times 10 \text{ filaments}/\approx 7.5 \text{ mm})] \approx 33\%.$$

High porosity proximate to a midpoint of the device **80** may provide good fluid flow to efferent vessels. Low porosity proximate to the first end **81** of the device **80** may provide good scaffolding properties.

In some embodiments, the device **80** further comprises a radiopaque marker **88** proximate to the first end **81** and/or a radiopaque marker **89** proximate to the second end **82**. In certain embodiments, the radiopaque marker **88** may extend at least partially into the aneurysm **20** when the device **80** is positioned at the junction of a bifurcation. In some embodiments, the radiopaque markers **88**, **89** may comprise a sleeve positioned or wrapped around the filaments **84**, thereby coupling the filaments **84**. The radiopaque markers **88**, **89** may aid in positioning the device **80** at the junction of a bifurcation.

In some embodiments, the device **80** further comprises a covering (e.g., comprising a porous or non-porous polymer) proximate to the first end **81**. In some embodiments, the covering improves the scaffolding properties of the device **80** by reducing the porosity at the first end **81**, thereby further inhibiting the herniation or prolapse of embolic material from the aneurysm **20**. In certain embodiments, the covering may be attached to the device **80** by sewing the covering from a pre-formed thin film. In certain embodiments, the covering may be mechanically attached (e.g., wrapped around, looped through, etc.) the filaments **84**. In certain embodiments, the covering may be deposited (e.g., via physical vapor deposition, chemical vapor deposition, etc.) on the filaments **84**. Other portions of the device **80** may also comprise a covering.

FIGS. **9**A-**9**C illustrate an example embodiment of a method for treating an aneurysm **20** using the device **80**. FIG. **9**A illustrates a confluence of afferent and efferent vessels or "junction" at a bifurcation **60** having an aneurysm **20**. In some embodiments, the vessels are neurovascular or cranial. The aneurysm **20** is illustrated with a plurality of embolization coils **62** having been inserted in the fundus **22** of the aneurysm **20**. It will be appreciated that the embolization coils **62** may be a single embolization coil or other embolic material. A catheter **92** (e.g., a microcatheter), at least partially containing a constricted or compressed device **80**, is also shown in the afferent vessel. The catheter **92** is small enough and flexible enough to be routed through the vasculature and situated proximate to the aneurysm **20**. In some embodiments, the embolization coils **62** are inserted in the fundus **22** of the aneurysm **20** using the catheter **92**. In some embodiments, the embolization coils **62** are inserted in the fundus **22** of the aneurysm **20** using a different catheter. In certain such embodiments, a guidewire may be used to guide both catheters.

FIG. **9**B illustrates the bifurcation **60** after the device **80** has been deployed from the catheter **92** (e.g., by being pushed out with a plunger, by retracting the catheter **92** while the device **80** remains stationary, etc.). After being deployed from the catheter **92**, the device **80** may expand. In some embodiments, the device **80** comprises a self-expanding and/or a shape-memory material that automatically expands towards an uncompressed state or expands towards an uncompressed state upon the application of warm fluid (e.g., saline). The device **80** may substantially conform to the shape of the junction of the bifurcation **60** (e.g., not substantially including portions extending into the afferent and efferent vessels) and locks into place across the ostia of the afferent and efferent vessels and the neck **24** of the aneurysm **20**. The device **80** at least partially covers the neck **24** of the aneurysm **20** as well as the afferent and efferent vessels, but does not need to divert flow. The device **80** acts as a scaffolding to inhibit or prevent herniation or prolapse of objects such as the embolization coils **62** and/or thrombi out of the aneurysm **20**. The device **80** also allows perfusion of fluid (e.g., blood) from the afferent vessel(s) to the efferent vessel(s).

FIG. **9**C illustrates the bifurcation **60** after the device **80** has been released from the catheter **92**. In some embodiments, the device **80** is released mechanically (e.g., by a release mechanism). In some embodiments, the device **80** is released electrolytically (e.g., by applying a small current until a portion of the tail **83** proximal to the device **80** corrodes away, as illustrated by the gap **95**). The catheter **92** is then withdrawn from the bifurcation **60**, thereby leaving or permanently positioning the device **80** at the junction of the bifurcation **60**.

It will be appreciated that the term "permanently" does not mean that the device **80** is impossible to remove at a later time. In some embodiments, the device **80** may be retracted into the catheter **92** after being deployed from the catheter **92** (e.g., by pulling on the tail **83**). The device **80** may then be deployed, for example at a new angle, at a new rotational position, more proximal or distal to an afferent vessel and/or an efferent vessel, etc. For example, although the device **80** expands towards an uncompressed state after deployment, the resulting shape of the device **80** at the junction of the bifurcation **60** may vary depending on the details of the deployment from the catheter **92** because the device **80** adapts to the shape of the anatomy (e.g., due to the size, shape, number, etc. of the loops **82**). Once the user is satisfied with properties of the device **80** (e.g., position, tilt, rotation, shape, interaction with the vessels, etc.), the device **80** may be released as described herein.

In the embodiment illustrated in FIGS. **9**A-**9**C, the embolization coils **62** are inserted in the fundus **22** of the aneurysm **20** before the device **80** has been deployed from the catheter **92** (e.g., using the catheter **92** to insert the embolization coils **62**). In the embodiments illustrated in FIGS. **10**A-**10**C, the embolization coils **62** are inserted in the fundus **22** of the aneurysm **20** after the device **80** has been released from the catheter **92** (e.g., using the catheter **92** to insert the embolization coils **62**). Combinations are also possible. For example, the embolization coils **62** may be inserted in the fundus **22** of the aneurysm **20** after the device **80** has been deployed from the catheter **92**, but prior to the device **80** being released from the catheter **92**. For another example, the embolization coils **62** may be inserted into the fundus **22** of the aneurysm **20** after the device **80** has been deployed from the catheter **92** (e.g., in

a coil state), and the device **80** may be retracted and redeployed from the catheter **92** (e.g., in a final state).

FIG. **11** illustrates yet another example embodiment of a generally spherical vascular remodeling device **110**. It will be appreciated that the device **110** may be more compliant than the vasculature in which it is deployed such that it may be somewhat misshapen (e.g., non-spherical, for example as illustrated in FIG. **12**) after being deployed, and that the phrase "generally spherical" describes the shape of the device **110** when in an expanded (e.g., fully expanded) state. Additionally, the phrase "generally spherical" distinguishes the device **110**, which is generally uniform in each dimension in an expanded state, from tubular stents having a small radial dimension and a large longitudinal dimension in an expanded state. In some embodiments of a generally spherical device, an outer periphery of the device has a shape that deviates by between about 10% and about 25% from an outer periphery of a mathematically perfect sphere. In some embodiments, the device **110** has a length and a width that are within less than about 33% of each other (e.g., having a length of 6 mm and a width of 8 mm, having a length of 6 mm and a width of 8 mm). Embodiments in which the width is greater than the length may be advantageous due to a difference in porosity at a midpoint and an end proximate to an aneurysm. Embodiments in which the length is greater than the width may be advantageous for positioning a portion of the device **110** in a portion of the aneurysm **20** (e.g., to aid in embolization).

The device **110** comprises a first or distal end **111** and a second or proximal end **112** substantially opposite the first end **111**. The device **110** further comprises a plurality of filaments **114** extending between the first end **111** and the second end **112**. In the device **110** illustrated in FIG. **11**, the first end **111** extends inwardly and the second end **112** extends outwardly to form a generally spherical shape similar to a pumpkin, a garlic bulb, or a rutabaga. In some embodiments, the filaments **114** are coupled at a position proximal to a bend at a distal end of the device **110** (e.g., as illustrated by the dimension d in FIG. **11**). In certain embodiments, the filaments **114** are coupled at the first end **111** and/or the second end **112** (e.g., by adhering, welding, soldering, combinations thereof, and the like). In the embodiment illustrated in FIG. **11**, the device **110** comprises a lead or tail **113**, which may be used for releasing and/or retracting the device **110** after deployment, as described herein. In certain embodiments, the device **110** comprises a cut metallic sphere, a single filament, etc. It will be appreciated that a device in which the first end extends outwardly and the second end extends inwardly and a device in which the first end extends inwardly and the second end extends inwardly are also possible.

In certain embodiments, the device **110** is configured to be positioned at a junction of a bifurcation (e.g., a neurovascular bifurcation) comprising at least one afferent vessel, efferent vessels, and an aneurysm having a fundus and a neck. For example, in some embodiments, the device **110** is suitably dimensioned to fit in a junction of a bifurcation (e.g., having a diameter between about 2 mm and about 12 mm, having a diameter between about 6 mm and about 8 mm, having a diameter less than about 12 mm, having a diameter greater than about 2 mm). For another example, in some embodiments, the device **110** is less rigid than a junction of a bifurcation (e.g., due to the number of filaments **114**, the material of the filaments **114**, the thickness of the filaments **114**, the spacing of the filaments **114**, the shape of the filaments **114**, combinations thereof, and the like). In certain embodiments, the device **110** is configured to act as a scaffolding to inhibit or prevent herniation or prolapse of objects (e.g., embolization coils, thrombi, etc.) out of a neck of an aneurysm. For example, in some embodiments, the filaments **114** are dense enough at the neck of the aneurysm that objects cannot pass. In certain embodiments, the device **110** is configured to permit perfusion of fluid (e.g., blood) to efferent vessels of a bifurcation. For example, in some embodiments, the device **110** is substantially devoid of a covering, mesh, or other material between the filaments **114**, thereby allowing fluid to flow substantially unimpeded.

In some embodiments, at least one of the filaments **114** comprises a self-expanding and/or a shape-memory material (e.g., comprising Nitinol, CoCr alloy, etc.), thereby causing the device **110** to be self-expanding under certain conditions (e.g., not restrained by a catheter). In some embodiments, at least one of the filaments **114** comprises a different material than others of the filaments **114** (e.g., some filaments **114** comprising Nitinol and some filaments **114** comprising Nitinol and platinum). In some embodiments, at least one of the filaments **114** comprises a radiopaque material (e.g., platinum). In certain such embodiments, an even number of filaments **84** (e.g., two, four, etc.) comprises a radiopaque material (e.g., platinum). In some embodiments, at least one of the filaments **84** comprises a radiopaque material (e.g., platinum) at least partially wrapped (e.g., coiled) around a self-expanding material (e.g., Nitinol). In some embodiments, at least one of the filaments **84** comprises a self-expanding material with a radiopaque core (e.g., Nitinol with a platinum core) or a radiopaque coating (e.g., Nitinol coated with platinum, tantalum, etc. by physical vapor deposition, chemical vapor deposition, plating, etc.). It will be appreciated that the amount and type of radiopaque material used may depend, inter alia, on price, desired level of radiopacity, mechanical properties of the radiopaque material, and corrosion properties of the radiopaque material. In certain embodiments, the filaments **114** have a substantially circular or ovoid cross section section (e.g., embodiments, in which the filaments **84** comprise separate wires). In some embodiments, the filaments **114** have a substantially rectangular or flat cross section (e.g., embodiments, in which the filaments **84** comprise uncut portions of a metallic tube). Other shapes of filaments **114** and combinations of shapes of filaments **114** are also possible. In certain embodiments, the plurality of filaments **84** comprises between about six and about twelve filaments **114**. In certain embodiments, the plurality of filaments **114** comprises at least about six filaments **114**, at least about eight filaments **114**, or at least about twelve filaments **114**. Other numbers of filaments **114** are also possible.

The device **110** comprises a plurality of perforations or cells **116** between the filaments **114**. In certain embodiments, a percentage of the outer surface of the device **110** covered by the filaments **114** is between about 25% and about 40%. In certain embodiments, a percentage of the outer surface of the device **110** covered by the cells **116** is between about 60% and about 75%. Other porosities are also possible. In some embodiments, porosity distally increases between the second end **112** and an approximate midpoint and distally decreases between the approximate midpoint and the first end **111**.

In some embodiments, the device **110** further comprises a radiopaque marker **118** proximate to the first end **111** and/or a radiopaque marker **119** proximate to the second end **112**. In certain embodiments, the radiopaque marker **118** may extend at least partially into the aneurysm **20** when the device **110** is positioned at the junction of a bifurcation. In some embodiments, the radiopaque markers **118**, **119** may comprise a sleeve situated or wrapped around the filaments **114**, thereby

coupling the filaments **114**. The radiopaque markers **118**, **119** may aid in positioning the device **110** at the junction of a bifurcation.

In some embodiments, the device **110** further comprises a covering (e.g., comprising a porous or non-porous polymer) proximate to the first end **111**. In some embodiments, the covering improves the scaffolding properties of the device **110** by reducing the porosity at the first end **111**, thereby further inhibiting the herniation or prolapse of embolic material from the aneurysm **20**. In certain embodiments, the covering may be attached to the device **110** by sewing the covering from a pre-formed thin film. In certain embodiments, the covering may be mechanically attached (e.g., wrapped around, looped through, etc.) the filaments **114**. In certain embodiments, the covering may be deposited (e.g., via physical vapor deposition, chemical vapor deposition, etc.) on the filaments **114**. Other portions of the device **110** may also comprise a covering.

FIG. **12** illustrates an example embodiment of treating an aneurysm **20** using the device **110**. The junction at the bifurcation **60**, including the treated aneurysm **20**, illustrated in FIG. **12** may be the result of performing a method similar to the method described with respect to FIGS. **9**A-**9**C, the result of performing a method similar to the method described with respect to FIGS. **10**A-**10**C, combinations thereof, and the like.

As described above, the term "bifurcation" described herein is not limited to the particular vasculature illustrated in FIGS. **6**A-**7**C, **9**A-**10**C, and **12**, for example having efferent vessels at substantially different angles, having efferent vessels that are substantially different sizes, and/or having a different quantity of efferent vessels and/or the aneurysm of the bifurcation may be offset with respect to the junction (e.g., having a neck substantially open to one efferent vessel), tilted with respect to a plane created by the vessels (e.g., into or out of the page), etc.

FIG. **13** illustrates still another example embodiment of a generally spherical vascular remodeling device **130**. It will be appreciated that the device **130** may be more compliant than the vasculature in which it is deployed such that it may be somewhat misshapen (e.g., non-spherical) after being deployed, and that the phrase "generally spherical" describes the shape of the device **130** when in an expanded (e.g., fully expanded) state. Additionally, the phrase "generally spherical" distinguishes the device **130**, which is generally uniform in each dimension in an expanded state, from tubular stents having a small radial dimension and a large longitudinal dimension in an expanded state. In some embodiments of a generally spherical device, an outer periphery of the device has a shape that deviates by between about 10% and about 25% from an outer periphery of a mathematically perfect sphere. In some embodiments, the device **130** has a length and a width that are within less than about 33% of each other (e.g., having a length of 6 mm and a width of 8 mm, having a length of 6 mm and a width of 8 mm). Embodiments in which the width is greater than the length may be advantageous due to a difference in porosity at a midpoint and an end proximate to an aneurysm. Embodiments in which the length is greater than the width may be advantageous for positioning a portion of the device **130** in a portion of the aneurysm **20** (e.g., to aid in embolization).

The device **130** comprises a first or distal end **131** and a second or proximal end **132** substantially opposite the first end **131**. The device **130** further comprises a plurality of filaments **134** extending between the first end **131** and the second end **132**. In the device **130** illustrated in FIG. **13**, the first end **131** extends outwardly and the second end **132** extends outwardly to form a generally spherical shape similar to a twisted sphere (e.g., after rotating one or both ends **81**, **82** of the device **80** illustrated in FIG. **8** with respect to each other). In certain embodiments, the filaments **134** are coupled at the first end **131** and/or the second end **132** (e.g., by adhering, welding, soldering, combinations thereof, and the like). In contrast to the filaments **84** of the device **80** illustrated in FIG. **8**, which in some embodiments are straight enough to form a plane, the filaments **134** of the device **130** are longitudinally angled at or adjacent to at least the second end **132**. In the embodiment illustrated in FIG. **13**, the device **130** comprises a lead or tail **133**, which may be used for releasing and/or retracting the device **130** after deployment, as described herein. In some embodiments, deployment and/or retraction of the device **130** uses less force than retraction of, for example, the devices **50**, **80**, **110**. In certain embodiments, the device **130** comprises a cut metallic sphere, a single filament, etc.

In certain embodiments, the device **130** is configured to be positioned at a junction of a bifurcation (e.g., a neurovascular bifurcation) comprising at least one afferent vessel, efferent vessels, and an aneurysm having a fundus and a neck. For example, in some embodiments, the device **130** is suitably dimensioned to fit in a junction of a bifurcation (e.g., having a diameter between about 2 mm and about 12 mm, having a diameter between about 6 mm and about 8 mm, having a diameter less than about 12 mm, having a diameter greater than about 2 mm). For another example, in some embodiments, the device **130** is less rigid than a junction of a bifurcation (e.g., due to the number of filaments **134**, the material of the filaments **134**, the thickness of the filaments **134**, the spacing of the filaments **134**, the shape of the filaments **134**, combinations thereof, and the like). In certain embodiments, the device **130** is configured to act as a scaffolding to inhibit or prevent herniation or prolapse of objects (e.g., embolization coils, thrombi, etc.) out of a neck of an aneurysm. For example, in some embodiments, the filaments **134** are dense enough at the neck of the aneurysm that objects cannot pass. In certain embodiments, the device **130** is configured to permit perfusion of fluid (e.g., blood) to efferent vessels of a bifurcation. For example, in some embodiments, the device **130** is substantially devoid of a covering, mesh, or other material between the filaments **134**, thereby allowing fluid to flow substantially unimpeded.

In some embodiments, at least one of the filaments **134** comprises a self-expanding and/or a shape-memory material (e.g., comprising Nitinol, CoCr alloy, etc.), thereby causing the device **130** to be self-expanding under certain conditions (e.g., not restrained by a catheter). In some embodiments, at least one of the filaments **134** comprises a different material than others of the filaments **134** (e.g., some filaments **134** comprising Nitinol and some filaments **134** comprising Nitinol and platinum). In some embodiments, at least one of the filaments **134** comprises a radiopaque material (e.g., platinum). In certain such embodiments, an even number of filaments **84** (e.g., two, four, etc.) comprises a radiopaque material (e.g., platinum). In some embodiments, at least one of the filaments **84** comprises a radiopaque material (e.g., platinum) at least partially wrapped (e.g., coiled) around a self-expanding material (e.g., Nitinol). In some embodiments, at least one of the filaments **84** comprises a self-expanding material with a radiopaque core (e.g., Nitinol with a platinum core) or a radiopaque coating (e.g., Nitinol coated with platinum, tantalum, etc. by physical vapor deposition, chemical vapor deposition, plating, etc.). It will be appreciated that the amount and type of radiopaque material used may depend, inter alia, on price, desired level of radiopacity, mechanical

properties of the radiopaque material, and corrosion properties of the radiopaque material. In certain embodiments, the filaments **134** have a substantially circular or ovoid cross section (e.g., embodiments, in which the filaments **84** comprise separate wires). In some embodiments, the filaments **134** have a substantially rectangular or flat cross section (e.g., embodiments, in which the filaments **84** comprise uncut portions of a metallic tube). Other shapes of filaments **134** and combinations of shapes of filaments **134** are also possible. In certain embodiments, the plurality of filaments **84** comprises between about six and about twelve filaments **134**. In certain embodiments, the plurality of filaments **134** comprises at least about six filaments **134**, at least about eight filaments **134**, or at least about twelve filaments **134**. Other numbers of filaments **134** are also possible.

The device **130** comprises a plurality of perforations or cells **136** between the filaments **134**. In certain embodiments, a percentage of the outer surface of the device **130** covered by the filaments **134** is between about 25% and about 40%. In certain embodiments, a percentage of the outer surface of the device **130** covered by the cells **136** is between about 60% and about 75%. Other porosities are also possible. In some embodiments, porosity distally increases between the second end **132** and an approximate midpoint and distally decreases between the approximate midpoint and the first end **131**.

In some embodiments, the device **130** further comprises a radiopaque marker **138** proximate to the first end **131** and/or a radiopaque marker **139** proximate to the second end **132**. In certain embodiments, the radiopaque marker **138** may extend at least partially into the aneurysm **20** when the device **130** is positioned at the junction of a bifurcation. In some embodiments, the radiopaque markers **138**, **139** may comprise a sleeve situated or wrapped around the filaments **134**, thereby coupling the filaments **134**. The radiopaque markers **138**, **139** may aid in positioning the device **130** at the junction of a bifurcation.

In some embodiments, the device **130** further comprises a covering (e.g., comprising a porous or non-porous polymer) proximate to the first end **131**. In some embodiments, the covering improves the scaffolding properties of the device **130** by reducing the porosity at the first end **131**, thereby further inhibiting the herniation or prolapse of embolic material from the aneurysm **20**. In certain embodiments, the covering may be attached to the device **130** by sewing the covering from a pre-formed thin film. In certain embodiments, the covering may be mechanically attached (e.g., wrapped around, looped through, etc.) the filaments **134**. In certain embodiments, the covering may be deposited (e.g., via physical vapor deposition, chemical vapor deposition, etc.) on the filaments **134**. Other portions of the device **130** may also comprise a covering.

The device **130** may be positioned and retracted as described, for example, by performing a method similar to the method described with respect to FIGS. **9**A-**9**C, by performing a method similar to the method described with respect to FIGS. **10**A-**10**C, combinations thereof, and the like. As described above, the device **130** may be particularly advantageous for embodiments in which retraction and redeployment of the device **130** is likely.

FIG. **14** illustrates an example embodiment of a generally spherical vascular remodeling device **140** (e.g., having a football shape similar to the device **80**) at a stage of an example manufacturing process comprising cutting and shaping a metallic tube (e.g., a laser cut hypotube). In some embodiments, the starting tube has a diameter between about 0.5 mm and about 3 mm or between about 1 mm and about 2 mm (e.g., about 1 mm, about 1.5 mm, about 2 mm, etc.). Other diameters are also possible. The device has a first or distal end **141** and a second or proximal end **142** substantially opposite the first end **141**. A laser may cut out portions **146** of the tube, leaving a plurality of filaments **144** extending between the first end **141** and the second end **142**. In the embodiment illustrated in FIG. **14**, the filaments **144** are coupled at the first end **141** and the second end **142** (e.g., due to being integrally formed with the metallic tube and not cut away from each other). In some embodiments, a lead or tail, which may be used for releasing and/or retracting the device **140** after deployment, as described herein, may be attached to the device **140** (e.g., by adhering, soldering, welding, etc.). In certain embodiments, a tail **143** may be integral with the device **140** by being defined by the cut tube.

In some embodiments, the device **140** further comprises a radiopaque marker **148** proximate to the first end **141** and/or a radiopaque marker **149** proximate to the second end **142**. In certain embodiments, the radiopaque marker **148** may extend at least partially into the aneurysm **20** when the device **140** is positioned at the junction of a bifurcation. In some embodiments, the radiopaque markers **148**, **149** may be integral with the device by being defined by the cut tube. The radiopaque markers **148**, **149** may aid in positioning the device **140** at the junction of a bifurcation.

The cut tube can then be expanded into a generally spherical shape through shape setting using a heat treatment process. The shape setting process may include several steps comprising of successively increasing diameters of generally spherical shapes using appropriate tooling to stretch and confine the cut tube into a new shape while heat treating it. At the end of the each heat treatment step, the cut tube assumes the shape in which it was confined during the heat treatment process. This process is then repeated to form a slightly larger size and a shape closer to the end product. The final shape (e.g., a football shape similar to the device **80**) and size may obtained by several such steps. Other devices described herein (e.g., the devices **50**, **110**, **130**) may also be formed using cut a metallic tube that is reshaped after being cut, although it will be appreciated that the pattern of the initial cut may be different, such that details about possible materials, dimensions, porosities, deployment methods, possibly coverings, etc. are not provided.

Certain devices described herein may be advantageously used to treat aneurysms having a neck ratio (a ratio of fundus width to neck width) greater than about 2 to 1 and/or a neck width greater than about 4 mm. In treatment of such aneurysms, embolization coils may be prone to herniating into parent vessels because the size and/or shape of the aneurysm is not conducive to maintaining the coils in their inserted locus. In certain such embodiments, embolization coils are inserted in the fundus of the aneurysm after positioning a generally spherical device so that the embolization coils do not have an opportunity to herniate. It will be appreciated that certain devices described herein may also be used to treat aneurysms having a neck ratio less than about 2 to 1 and/or a neck width less than about 4 mm. In certain such embodiments, embolization coils are inserted in the fundus of the aneurysm before positioning a generally spherical device.

Certain devices described herein may advantageously be a single generally spherical device placed at a junction of a bifurcation rather than a plurality of tubular bifurcations. Certain such devices can span a neck of an aneurysm as well as arterial ostia. Positioning such devices may be less complicated, thereby reducing risks associated with, for example, than ensuring that a tubular device is properly anchored in an afferent vessel and in an efferent vessel.

In some embodiments in which embolic material was previously inserted in an aneurysm but has herniated, certain devices described herein may be used as a "rescue device" to push the herniated material back into the aneurysm and to act as a scaffolding to inhibit or prevent further herniation or prolapse of the embolic material. In certain such embodiments, deployment of such devices may advantageously avoid traversal of the junction comprising the herniated material by wires or a catheter (e.g., there is no need to traverse wires or a catheter past the junction into an efferent vessel for positioning of the device as is generally needed to position tubular devices such as the devices **42**, **44** illustrated in FIGS. **4**B and **4**C), which may cause the herniated material to become tangled and/or dislodged and which may cause rupture of the aneurysm.

Although this invention has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while several variations of the embodiments of the invention have been shown and described in detail, other modifications, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the invention. It should be understood that various features and aspects of the disclosed embodiments can be combined with, or substituted for, one another in order to form varying modes of the embodiments of the disclosed invention. Thus, it is intended that the scope of the invention herein disclosed should not be limited by the particular embodiments described above.

What is claimed is:

1. A method of treating an aneurysm at a bifurcation having an afferent vessel and efferent vessels having a junction, the aneurysm having a neck and a fundus, the method comprising:

advancing a catheter proximate to the junction of the bifurcation, the catheter at least partially containing a generally spherical vascular remodeling device in a compressed state;

expanding the device from the compressed state to an uncompressed state at the junction of the bifurcation;

withdrawing the catheter and leaving the device at the junction of the bifurcation, wherein the device acts as a scaffolding to inhibit herniation of objects out of the neck of the aneurysm, wherein the device permits perfusion of fluid to the efferent vessels, and

after the expanding the device, the withdrawing the catheter, and the leaving the device, inserting the objects in the fundus of the aneurysm, the objects comprising coils;

wherein the device comprises a first filament junction and a second filament junction substantially opposite to the first filament junction along a longitudinal axis, and a plurality of filaments, each of the plurality of filaments comprising a middle segment extending an entire distance from the first filament junction to the second filament junction, the middle segments forming the entirety of a generally spherical shape, each of the plurality of filaments having a first end region and a second end region, the first end regions coupled to each other forming the first filament junction, and the second end regions coupled to each other forming the second filament junction;

wherein the device further comprises a first sleeve around the first end regions at the first filament junction and extending outside an outer periphery of the generally spherical shape along the longitudinal axis;

wherein the device further comprises a second sleeve around the second end regions at the second filament junction and extending outside the outer periphery of the generally spherical shape along the longitudinal axis;

wherein the middle segments are unattached to one another between the first filament junction and the second filament junction; and

wherein, when the device is left at the bifurcation junction after the expanding, the plurality of filaments extend continuously in a direction along the longitudinal axis from the first end region to the second end region, with no longitudinal reversal of direction.

2. The method of claim **1**, wherein the bifurcation is a neurovascular bifurcation.

3. The method of claim **1**, wherein the device substantially conforms to a shape of the bifurcation.

4. The method of claim **1**, wherein the plurality of filaments comprise a self-expanding or a shape-memory material and wherein expanding the device comprises allowing the device to expand towards the uncompressed state.

5. The method of claim **1**, further comprising releasing the device from the catheter after expanding the device.

6. The method of claim **5**, wherein releasing the device comprises mechanically releasing the device from the catheter.

7. The method of claim **5**, wherein releasing the device comprises electrolytically releasing the device from the catheter.

8. The method of claim **5**, further comprising: after expanding the device, retracting the device into the catheter; redeploying the device from the catheter; and re-expanding the device.

9. The method of claim **1**, wherein a ratio of fundus width to neck width is greater than about 2 to 1.

10. The method of claim **1**, wherein neck width is greater than about 4 mm.

11. A method of treating an aneurysm at a bifurcation having an afferent vessel and efferent vessels having a junction, the aneurysm having a neck and a fundus, the method comprising:

advancing a catheter proximate to the junction of the bifurcation, the catheter at least partially containing a generally spherical vascular remodeling device in a compressed state, the device comprising:

a plurality of filaments having (i) a plurality of middle segments, each having an entire length extending from a proximal end to a distal end, the proximal end and the distal end extending outwardly to form a generally spherical shape having an outer periphery, the plurality of middle segments being unattached to each other between the proximal ends to the distal ends (ii) a plurality of proximal segments proximal to the middle segments and being coupled together at the proximal location outside the outer periphery of the generally spherical shape, and (iii) a plurality of distal segments distal to the middle segments and being coupled together at the distal location outside the outer periphery of the generally spherical shape and substantially opposite to the proximal location along a longitudinal axis of the device;

a proximal sleeve positioned around the plurality of proximal segments at the proximal location; and

a distal sleeve positioned around the plurality of distal segments at the distal location;

expanding the device from the compressed state to an uncompressed state at the junction of the bifurcation;

withdrawing the catheter and leaving the device at the junction of the bifurcation, wherein the device acts as a scaffolding to inhibit herniation of embolic coils out of the neck of the aneurysm, wherein the device permits perfusion of fluid to the efferent vessels, and

after expanding the device, withdrawing the catheter, and leaving the device at the junction of the bifurcation, inserting the embolic coils through the device and into the fundus of the aneurysm.

12. The method of claim **11**, wherein the device is substantially devoid of a covering, mesh, or other material between the filaments, thereby allowing fluid to flow substantially unimpeded there through.

13. The method of claim **11**, wherein each of the filaments has a substantially rectangular cross section.

14. The method of claim **11**, wherein the generally spherical shape is a twisted sphere.

15. The method of claim **14**, wherein the twisted sphere is formed by the proximal end relative to the distal end.

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